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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, 2019

**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.)

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**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)

*Copy to:*

**Henry Nisser, Esq.  
Alzamend Neuro, Inc.  
100 Park Avenue, Suite 1658  
New York, New York 10017  
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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. 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***

We were formed on February 26, 2016, as Alzamend Neuro, Inc. under the laws of the State of Delaware. We were 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**”). We have 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 caused by Alzheimer’s.

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

On May 1, 2016, we obtained a royalty-bearing, exclusive worldwide license from the University of South Florida Research Foundation, Inc. (the "Licensor"), 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 September 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 fourth 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, a consultant for Alzamend Neuro, 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 80 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, which bind to and activate sensory nerves in the periphery that are transmitted to the central nervous system, and nitric oxide in activated microglia. We continue to work with one of the inventors of this therapeutic, at the USF Morsani College of Medicine; 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 (the "University"), have designed, synthesized and characterized this ionic cocrystal of lithium, which we have 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 mouse models of Alzheimer's. 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 we have licensed and will first move to commercialization is an ionic cocrystal of lithium for the treatment of Alzheimer's 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 have developed a new lithium cocrystal composition and method of preparation that allow 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. 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.

With this in mind, this team of inventors from the University have designed, synthesized and characterized a new ionic cocrystal of lithium that we have 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. 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. Based upon the existing data available in the public domain supplanted with the knowledge that the FDA has about lithium, we do not believe there is a need to conduct any further preclinical studies and have therefore submitted a pre-IND application to the FDA in July 2019 that precludes any further preclinical studies. When we receive feedback from the FDA from the pre-IND, expected in late September 2019, we anticipate beginning the process of finalizing the IND application and receiving approval to begin a Phase 1 Clinical Trial with human subjects in the fourth quarter of 2019. Although we cannot provide any assurances, we believe that LiProSal<sup>TM</sup> is an ideal candidate to receive both Breakthrough Therapy designation as well as 505(b)(2) regulatory pathway for new drug approvals.

A product can be designated as a Breakthrough Therapy designation if it is intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). A drug that receives Breakthrough Therapy designation is eligible for fast track designation features, intensive guidance on an efficient drug development program and FDA organizational commitment involving senior managers. We further believe that LiProSal<sup>TM</sup> is ideally situated for 505(b)(2) regulatory pathway for new drug approvals. The 505(b)(2) regulatory pathway provides manufacturers with an opportunity to acquire FDA approval without performing all the work that's required with an NDA. Those drugs that qualify for the 505(b)(2) regulatory pathway are an option for drugs with a new aspect related to indication, dosage form or regimen, strength, combination with other products, or other unique traits. If we receive approval through the 505 (b)(2) regulatory pathway LiProSal<sup>TM</sup> is eligible for 3-5 years of market exclusivity during which period LiProSal<sup>TM</sup> would be protected from competitors. If we are successful receiving Breakthrough Therapy designation and 505(b)(2) regulatory pathway for new drug approvals, we believe we can receive FDA approval for LiProSal<sup>TM</sup> in four years.

LiProSal<sup>TM</sup> will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it or 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 we may be unable to generate the revenue we have forecast 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 our business or acquire additional IP as we have planned, we will not become profitable with this therapeutic agent, and we may be unable to continue our operations.

The other patented solution that we have licensed to move to commercialization is CAO22W, 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 the immune system through immunomodulation. We entered into an exclusive license agreement with sublicensing terms (Agreement #LIC16118) with an effective date of May 1, 2016, as amended on August 17, 2017, and May 7, 2018 (the "Effective Date"), by and between the University of South Florida Research Foundation, Inc. ("Licensor"), a direct support organization of the University of South Florida ("University").

Beta amyloid protein has been directly linked to Alzheimer's 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. In a healthy brain, protein fragments such as amyloid beta peptide 1-42 are broken down and eliminated. However, in Alzheimer's, the fragments accumulate to form hard, insoluble plaques. 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 we are currently in the midst of completing its preclinical development and have begun both the 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, we began a toxicological preclinical 6-month study for CAO22W with Charles River Laboratories, Inc. ("CRL") in compliance with FDA requirements. Upon conclusion of this toxicological study, anticipated to occur in the fourth quarter of 2019, we expect 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 we may be unable to generate the revenue we have forecast 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 our business or acquire additional IP as we have planned, we will not become profitable with this therapeutic agent, 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 \$290 billion in 2019 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, with more than 5.8 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 within which 1 in 3 individuals have Alzheimer's. Women are 2½ times more likely to die from Alzheimer's than from cancer.

The rate of deaths related to Alzheimer's increased by 54.5 percent over 15 years, according to a report issued on May 27, 2017, by the U.S. Centers for Disease Control and Prevention. There were 93,541 deaths related to Alzheimer's 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 5.8 million people in the U.S., but that number is expected to rise dramatically in people over the age of 65 to 14 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 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 human clinical trials administered by the FDA and ultimately, if successful, potentially make it available 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. In July 2019, we submitted a Pre-IND application to the FDA for our first product candidate, LiProSal™, an ionic cocrystal of lithium for the treatment of Alzheimer's and a method of preparation for other pharmaceutical and industrial purposes.

We are in the midst of completing a preclinical toxicology study with CRL for our second product candidate, CAO22W. Working with our regulatory consultant, TAMM Net, we have already begun 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 80 human participants, contingent upon guidance from the FDA. The FDA will provide 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.

We 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. We have also retained a division of the international Swiss manufacturer, Lonza, to develop the manufacturing protocols, processes and procedures for CAO22W. Lonza is the worldwide leader in producing immunological proprietary and contracted pharma solutions. We anticipate selecting Emory University as the host for the Phase 1 Clinical Trial, which will be led by Dr. Hajjar at the Emory Clinic.

In November 2018, we adopted a Charter for our Scientific Advisory Board ("SAB") and have announced the appointment of two SAB members, Dr. Thomas Wisniewski and Dr. Eric McDade. The SAB members have clinical specializations, including extensive experience with AD and other neurological diseases. We intend to rely on this advisory group of experts to help guide our therapies through the related scientific and manufacturing initiatives.

The continuation of our current plan of operations to completing our IND application and beginning the series of human clinical trials for each of our therapeutics requires us to promptly raise significant additional capital. If we are successful in raising capital, we believe that we will have sufficient cash resources to fund our operations.

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*

We have 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 that we have licensed. We 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*

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

We obtained two royalty-bearing, exclusive worldwide licenses from the Licensor, originally called LisPro, now given the trade name of LiProSal™, 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.

We are 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.

## Our Product Candidates

Although aging is considered to be the most important risk factor for the development of Alzheimer's, many other factors associated with aging have been proposed as additional independent or interactive causes. It is likely that most age-related diseases could be attributed, at least in part, to an imbalance and senescence of the immune system. Current drugs approved by the FDA for Alzheimer's only address symptoms and provide no benefit to the impaired immune system in Alzheimer's. This has motivated our team to develop a unique approach for combating Alzheimer's, namely through immunotherapy and our product candidate, CAO22W.

Recent progress in the treatment of neurodegenerative diseases, such as Alzheimer's, has demonstrated that both active and passive immunotherapies can slow down, to some degree, the progress of disease as demonstrated in clinical trials through the measurement of neuropathological and cognitive/behavioral endpoints. However, to our knowledge, no current therapy focuses on immune modulation or addresses an impaired immune system, which can obviously adversely affect the efficacy of active vaccines and immunotherapies. Therefore, we have concluded 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.

We believe that synthetic mutants of the amyloid beta ("A $\beta$ ") peptide with a mutation in amino acid 22, designated as CAO22W, represent the best candidate to break immune tolerance in elderly subjects, resulting in enhanced immune responsiveness. This is done through the sensitization of dendritic cells ("DC"), which are found in blood in an immature state, with the mutant A $\beta$  peptide. These DCs then are used as a cell-based vaccine. We believe that this approach has several major advantages over most immune-based and other approaches against Alzheimer's currently in development, based on the following: (i) the treatment uses the patient's blood cells as a source of therapy, minimizing the concern for treatment failure, while maximizing the safety profile of the vaccine; (ii) the treatment specifically targets the pathological isoforms, proteins that have a similar but not an identical amino acid sequence, of A $\beta$ , avoiding robust autoimmune responses and using a synthetically mutated pre-aggregated A $\beta$  with a point mutation in the T-cell epitope; (iii) use of DC-based vaccines can serve as a self-adjuvant to modulate and enhance both the innate and acquired (antibody and cellular based) immune system, without the generation of toxicity, and (iv) DC-based vaccines have been used safely in cancer treatment for a number of years.

In summary, our data have demonstrated that these mutant-peptide sensitized-DCs 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.

Researchers at the University have developed an ionic cocrystal of lithium for the treatment of Alzheimer's 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 University's inventors have developed a new lithium co-crystal composition and method of preparation that requires 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. 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.

With this in mind, the University's inventors have designed, synthesized and characterized a new ionic co-crystal of lithium, LiProSal™. LiProSal™ 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™ is targeted to be a major improvement over current lithium-based treatments and may also constitute a means of treating Alzheimer's.

## Our Science

Therapeutic Drug	Synopsis	Strength	Status
LiProSal™	<ul style="list-style-type: none"> <li>Use of patented Ionic Cocystal (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 Cocystal 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(b)(2) clinical trial pathway from FDA</li> <li>FDA has established a separate fast-track clinical process for Cocystal based technologies</li> <li>Accelerated path for the treatment of Alzheimer's, deemed "unmet need" by the FDA</li> </ul>	<ul style="list-style-type: none"> <li>Filing pre-IND and IND in Q3 2019</li> <li>Commencing human clinical trials in Q4 2019</li> </ul>
CAO22W	<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-1772)</li> </ul>	<ul style="list-style-type: none"> <li>This is the only therapeutic vaccine designed for the treatment and prophylactics 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 cause in the development/progression of AD from recent Phase II Clinical Trial results released by Biogen/Esai</li> <li>Accelerated path for the treatment of Alzheimer's, deemed "unmet need" by the FDA.</li> </ul>	<ul style="list-style-type: none"> <li>Completing pre-clinical studies and filing pre-IND in Q3 2019</li> <li>Filing IND in Q4 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 \$290 billion dollars in 2019 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. We were formed to commercialize patented intellectual property in this space, by funding it from its present state through FDA Clinical Trials and ultimately, if successful, make it available to the global market. Additionally, we are supporting ongoing research at the USF Health College of Medicine and plan 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 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 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 Alzheimer's today - 5.8 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 jumped by 54.5 percent over 15 years, according to a 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 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 5.8 million people in the U.S., but that number is expected to rise dramatically in people over the age of 65 to 14 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. We intend to outsource the manufacturing of our 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, we have 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, Switzerland, with major facilities in Europe, North America and South Asia. Lonza was established in the late 19th-century in Switzerland. Lonza 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 both safety and efficacy more rigorously.
- 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 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™ 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. Any delay in obtaining, or failure to obtain, regulatory approval for CAO22W or LiProSal™, or obtaining approval only 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 an 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™ and may furthermore state to the FDA that to our knowledge, no extraordinary circumstances exist that would 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 significantly changed 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 requires discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which increases 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 Economic Area**”). 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 Economic Area; 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 Economic Area 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 authorizations in the United States for LiProSal<sup>TM</sup> and CAO22W in the latter 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. Essentially, 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 the 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., its 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, unfair competition and other laws and regulations.

### **Overview of Alzheimer's**

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 5.8 million individuals in the US. Alzheimer's is also the sixth leading cause of death across all ages in the United States and its prevalence is expected to quadruple by 2050. Per the 2010 U.S. Census and the Chicago Health and Aging Project, a population-based study of chronic health conditions of older people, the average annual incidence in people ages 65-74 was 0.4 percent (meaning four of every 1,000 people will develop Alzheimer's in any given year); in people ages 75-84, the annual incidence was 3.2 percent (32 of every 1,000 people), and for ages 85 and older (the "oldest-old"), the incidence was 7.6 percent (76 of every 1,000 people). It is estimated that the cost of caring for people with Alzheimer's and other dementias will increase from an estimated \$290 billion in 2019 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 or other dementias. It is estimated by the Alzheimer's Association that in 2019 caregivers to people with Alzheimer's will provide 18.5 billion hours of care valued at \$234 billion.

The cause and progression of Alzheimer's are not well understood. As of 2019, more than 2,085 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 constitutes 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, to our knowledge, 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, we do not own a patent although we do possess a license for an immunotherapy technology and two licenses for a lithium salt and proline co-crystal technology from the University.

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 us 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 our employees, consultants or any 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.

We currently possess four service trademarks with the U.S. PTO that include our corporate name, Alzamend Neuro; two for our corporate slogan and one for our trade name, LiProSal™.

## 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

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

### Cerebrospinal Fluid (CSF)

CSF samples and protein assays of particular analytes remain today the best tools in the diagnosis of Alzheimer's 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 (inpatient 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 test 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, we had one full-time and two part-time employees. The services of two former officers and Executive Chairman of Alzamend were provided pursuant to the terms of a management services agreement (the “**MSA**”) entered into with Avalanche International Corp. (“**Avalanche**”), a related party, on May 1, 2016. In 2018, we retained each officer directly which provided us with management, consulting and financial services. Such services included advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorneys, financial advisors and other professionals. The term of the MSA, as amended, was for the period May 1, 2016 to December 31, 2018, with Avalanche having initially received \$40,000 per month and, beginning February 2017, receiving \$20,000 per month for the remainder of 2017. The MSA was terminated as of December 31, 2018. We accepted the resignation of our previous President and CEO, Philip Mansour, effective on November 18, 2018, and appointed Mr. Stephan Jackman as CEO as of November 30, 2018. Mr. Jackman is a full-time executive with extensive scientific and medical experience in developing immunotherapies and there commercialization to lead our activities. As of December 15, 2018, we accepted the resignation of our former CFO, William B. Horne and appointed our current CFO, Kenneth S. Cragun.

## **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**

We currently maintain our corporate offices at the University’s 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, when evaluating our company's prospects. 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 you may have made or could make in the future. 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.**

We were incorporated on February 26, 2016 and commenced operations shortly thereafter. Accordingly, we have a very limited 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 we will achieve or sustain profitability. Our 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, our ability to develop and market new products, control costs, and general economic conditions. We cannot assure you that we 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 shares of Common Stock by management and affiliated parties represents approximately 64.51% of our 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 may delay or frustrate the removal of incumbent directors and may prevent or delay a merger, tender offer or proxy contest involving our 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. Such shares have significant voting power, among other terms. Further, we may designate and issue separate classes of preferred stock that may entitle their holder(s) to exercise significant control over us. Consequently, anyone to whom or which 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 us. 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 us. 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 our 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, 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, 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 our 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 control of our company.

### **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 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 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, it is extremely unlikely that we will be able to generate any significant cash from our operating activities in the foreseeable 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 we will be able to generate any investor interest in our securities. Further, any financing that we may wish to enter into may be subject to the consent of Spartan Capital Securities, LLC (“**Spartan**”) and there can be no assurance that Spartan will provide its consent to any such financing. 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, we have generated no revenues and have incurred losses. As of April 30, 2019, we had cash of \$42,606 and an accumulated deficit of \$7,375,633. Since our inception, we have incurred recurring losses and reported losses for the year ended April 30, 2019, of \$4,862,496. The report of our independent registered public accounting firm on our April 30, 2019, financial statements includes a going concern explanatory paragraph which states that there is substantial doubt regarding our 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 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 the 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 requires us 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 that we pay combined royalty payments of four and one-half percent (4.5%) on net sales of products developed from the licensed technology. We have 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 of Common Stock equal to three percent (3%) of the sum of the total number of such shares issued and outstanding plus any securities that are convertible into or exercisable or exchangeable for shares of Common Stock until we have received a total of \$5 million in cash in exchange for our equity securities. Additionally, we are 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	Upon IND application filing	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

**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 we fail 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 us while the Licensor remains the owner of any of our equity securities. Further, if we issue 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 Commons 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 the Licensor, we could lose license rights that are important to our business.**

We are a party to these License Agreements with the Licensor 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 the Licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license, 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 the Licensor. 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™ or CAO22W following regulatory approval, whether alone or in collaboration with others; and
- acceptance of LiProSal™ or CAO22W by 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 LiProSa<sup>TM</sup>, 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 LiProSa<sup>TM</sup> 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, with other entities possibly 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 LiProSa<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 LiProSa<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 LiProSa<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 LiProSa<sup>TM</sup> or CAO22W, or limit the scope of any approved label or market acceptance.**

If LiProSa<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 LiProSa<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™ 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 from the norm, 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™ 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™ 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™ 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™ 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™ 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™, 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™, 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™ 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™ 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™, 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. 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<sup>TM</sup>, CAO22W or any future product candidates, conduct our in-licensing and development efforts or commercialize LiProSal<sup>TM</sup>, CAO22W or any of our future product candidates.**

Our future growth and success depend 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 our consultant, Dr. Chuanhai Cao, the neuroscientist who developed CAO22W, as well as the senior scientists on Dr. Cao's medical research team and Dr. Roland "Doug" Shytle, one of the investors of LiProSal<sup>TM</sup> 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<sup>TM</sup> or CAO22W. It is possible that current or former employees of ours 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 without a suitable replacement having been identified prior to such departure 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™, CAO22W or any future product candidates is threatened, it could threaten our ability to commercialize LiProSal™, 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™, 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™, 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™ 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.

On May 29, 2018, we implemented a 1-for-4 Reverse Stock Split of our 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 our pre-Reverse Stock Split Common Stock were combined and reclassified into one share of the 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 and their respective exercise prices were increased by a factor of four. 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. Neither the authorized shares of capital stock nor the par value per share of the Common Stock was affected by the Reverse Stock Split.

**RESULTS OF OPERATIONS FOR THE YEARS ENDED APRIL 30, 2019 AND 2018**

The following table summarizes the results of our operations for the years ended April 30, 2019 and 2018.

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

	<b>For the Year Ended April 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>OPERATING EXPENSES</b>		
Research and development	\$ 3,700,083	\$ 323,403
General and administrative	1,308,800	575,027
Total operating expenses	<u>5,008,883</u>	<u>898,430</u>
<b>Loss from operations</b>	(5,008,883)	(898,430)
<b>OTHER INCOME (EXPENSE), NET</b>		
Interest income - related party	146,387	7,341
Interest expense	-	(30,259)
Interest expense - debt discount	-	(10,315)
<b>Total other income (expense), net</b>	<u>146,387</u>	<u>(33,233)</u>
<b>NET LOSS</b>	<u>\$ (4,862,496)</u>	<u>\$ (931,663)</u>
<b>Basic and diluted net loss per common share</b>	<u>\$ (0.08)</u>	<u>\$ (0.02)</u>
<b>Basic and diluted weighted average common shares outstanding</b>	<u>58,843,040</u>	<u>45,389,196</u>

## Revenue

Alzamend Neuro, Inc. was formed on February 26, 2016, to acquire and commercialize patented intellectual property and know-how to prevent, treat and cure the crippling and deadly disease, Alzheimer's. We currently have only two product candidates, CAO22W and LiProSal<sup>TM</sup>. These products are in the early stage of development and will require extensive clinical study, review and evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they and any successors could provide us with any revenue. We did not generate any revenues during the years ended April 30, 2019 and 2018, 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, 2019 and 2018, were \$1,308,800 and \$575,027, respectively. As reflected in the table below, general and administrative expenses primarily consisted of the following expense categories: management services, professional fees, stock compensation expense, salaries and benefits, and advertising and promotion. The remaining general and administrative expenses of \$85,360 and \$55,298, respectively, primarily consisted of payments for consulting, transfer agent fees, travel, and other office expenses, none of which is significant individually.

	For the Year Ended April 30,	
	2019	2018
Management services	\$ 160,000	\$ 240,000
Professional fees	545,771	249,820
Stock compensation expense	396,170	-
Salary and benefits	96,460	-
Advertising and promotion	25,039	29,909
Other general and administrative expenses	85,360	55,298
Total general and administrative expenses	\$ 1,308,800	\$ 575,027

### Management services

As of April 30, 2019, we had two full-time and one part-time employee. We accepted the resignation of our previous President and CEO, Philip Mansour, effective on November 18, 2018, and appointed Mr. Stephan Jackman as CEO as of November 30, 2018. Mr. Jackman is a full-time executive with extensive scientific and medical experience in developing immunotherapies and their commercialization to lead Alzamend's activities. As of December 15, 2018, we accepted the resignation of our former CFO, William B. Horne and retained our current CFO, Kenneth S. Cragun. Prior to hiring Mr. Jackman and Mr. Cragun, the services of our two officers and Executive Chairman were provided pursuant to the terms of an MSA entered into with Avalanche, a related party, on May 1, 2016. Avalanche provided management, consulting and financial services to us. 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. We 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, 2019 and 2018, we recognized \$160,000 and \$240,000, respectively, in management fees in connection with this agreement. At April 30, 2019 and April 30, 2018, \$75,000 and \$3,000, respectively, was included within related party payable on our balance sheet. The MSA expired 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, 2019 and 2018, we reported professional fees of \$545,771 and \$249,820, respectively, which are principally comprised of the following items:

*Year Ended April 30, 2019*

- In June 2017, we 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 us with strategic introductions, assisting management with enhancing corporate and shareholder value and introducing us to potential investors. In December 2017, since the maximum amount was raised in a prior private placement, we 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, 2019, we recorded an expense of \$280,000 in connection with this consulting agreement.
- During the year ended April 30, 2019, we incurred \$130,524 in legal fees.
- During the year ended April 30, 2019, we incurred \$75,903 in audit fees.

*Year Ended April 30, 2018*

- During the year ended April 30, 2018, we incurred \$82,202 in audit fees.
- During January 2017, we 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 our company. During the year ended April 30, 2018, we recorded an expense of \$35,617 as a result of these two consulting agreements.
- During the year ended April 30, 2018, we recorded an expense of \$93,333 in connection with the Spartan consulting agreement referred to above.

*Advertising and promotion*

During the years ended April 30, 2019 and 2018, we incurred \$25,039 and \$29,909, respectively, in advertising and promotion related expenses. The majority of these expenditures was related to direct advertising of our Offering Statement on Google and Facebook and the development of a web and social media strategy.

**Research and development expenses**

Research and development expenses for the years ending April 30, 2019 and 2018, were \$3,700,083 and \$323,403, respectively. As reflected in the table below, research and development expenses primarily consisted of licenses and fees as well as professional fees.

	<b>For the Year Ended April 30,</b>	
	<b>2019</b>	<b>2018</b>
Licenses and fees	\$ 2,489,600	\$ 219,162
Professional fees	1,142,887	101,277
Other research and development expenses	67,596	2,964
Total research and development expenses	<u>\$ 3,700,083</u>	<u>\$ 323,403</u>

*Licenses and fees*

There are certain initial license fees and milestone payments required to be paid to the University and the USF Health Byrd Alzheimer's Institute, a multi-disciplinary center at the University, 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 us to pay royalty payments of 4% on net sales of products developed from the licensed technology while the License Agreements for LiProSal™ requires us to pay combined royalty payments of four and one-half percent (4.5%) on net sales of products developed from the licensed technology. We have already paid an initial license fee of \$200,000 for CAO22W and \$60,000 of an initial license fee of \$200,000 for LiProSal™. 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™ technologies, the Licensor received 2,227,923 shares Common Stock. Additionally, we are required to pay milestone payments on the due dates to the Licensor for the license of the CAO22W technology and for the LiProSal™ technologies

During the years ended April 30, 2019 and 2018, we incurred \$2,227,923 and \$218,417, respectively, in non-cash charges from issuances of Common Stock to the Licensor.

#### *Professional fees*

The second largest component of our research and development expenses is professional fees. During the years ended April 30, 2019 and 2018, we reported professional fees of \$1,142,887 and \$101,277, respectively, which are principally comprised of professional fees incurred by us during the year ended April 30, 2018, are attributed to various types of scientific services, including FDA consulting services. The increase in professional fees during the year ended April 30, 2019, relates primarily to fees incurred to conduct a preclinical toxicology mice study and an evaluation of CAO22W.

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

During the year ended April 30, 2019, we reported other income from related parties of \$146,387.

During the year ended April 30, 2018, we reported other expense, net, 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. At April 30, 2019 and 2018, we had no outstanding borrowings.

#### *Current and deferred income taxes*

We have made the decision to fully reserve our net deferred tax assets. As a result of this decision, we did not record an income tax benefit during the year ended April 30, 2019 and 2018.

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, we have established a 100% valuation allowance.

#### **LIQUIDITY AND CAPITAL RESOURCES**

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern. As of April 30, 2019, we had cash of \$42,606 and an accumulated deficit of \$7,375,633. We have incurred recurring losses and reported losses for the year ended April 30, 2019 totaled \$4,862,496. In the past, we have financed its operations principally through issuances of promissory notes and equity securities. During the year ended April 30, 2019, we continued to obtain additional equity and debt financing.

We expect to continue to incur losses for the foreseeable future and need to raise additional capital until we are able to generate revenues from operations sufficient to fund our development and commercial operations. Based on our current business plan, we believe that our cash and cash equivalents at April 30, 2019, 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 we have access to capital resources through potential public or private issuance of debt or equity securities. However, we cannot be certain that additional funding will be available on acceptable terms, or at all, in which case we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product. We may also be required to (a) seek collaborators for our product at an earlier stage than otherwise would be desirable and on terms that would be less favorable than might otherwise be available; or (b) relinquish or otherwise dispose of rights to technology or our product that we would otherwise seek to deploy or commercialize. These matters raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might become necessary should we be unable to continue as a going concern.

On March 20, 2019, we entered into securities purchase agreements for the purchase of 157,346 shares of Common Stock for a total purchase price of \$236,023, or \$1.50 per share with 78,672 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance. The purchase price of \$236,023 was paid in cash.

On April 30, 2019, we entered into a securities purchase agreement for the purchase of 10,000,000 shares of Common Stock for a total purchase price of \$15,000,000, or \$1.50 per share with 5,000,000 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance. The total purchase price of \$15,000,000 was in the form of a note receivable with a 12-month term from Ault Life Sciences Fund, LLC, a related party. While this transaction did not provide immediate liquidity, as the note receivable is paid, we expect this to be a source of future capital resources.

On April 10, 2018, Avalanche issued a promissory note us (the “AVLP Note”) to evidence our 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. During the year ended April 30, 2019, we have provided loans to Avalanche in the principal amount of \$792,085, of which \$558,000 was repaid. The balance outstanding on the AVLP Note as of April 30, 2019, was \$205,915.

## CONTRACTUAL OBLIGATIONS

On May 1, 2016, we entered into the License Agreement with the Licensor pursuant to which the Licensor granted us 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, we were required to pay a license fee of \$100,000 on June 25, 2016, and December 31, 2016. As an additional licensing fee, the Licensor is entitled to receive that number of shares of our 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 we have received a total of \$5 million in cash in exchange for our equity securities. Additionally, we are required to pay milestone payments on the due dates to Licensor for the license of the technology, as follows:

<u>Payment</u>	<u>Due Date</u>	<u>Event</u>
\$ 50,000	Upon IND application filing	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 Licensor may terminate the License Agreement.

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 us while Licensor remains the owner of any equity securities of our company. Further, if we issue 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 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.

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™ licenses, in the aggregate, we are required to pay initial license fees of \$50,000 no later than July 31, 2018, and \$150,000 no later than March 31, 2019. 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 issued and outstanding shares. Additionally, we are 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

#### **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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Stephan Jackman	44	Chief Executive Officer
Kenneth S. Cragun	58	Chief Financial Officer
Henry C. W. Nisser	51	General Counsel and Executive Vice President
Milton C. Ault, III	49	Executive Chairman & Director
Phillip E. Mansour	51	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 began working for Alzamend on November 1, 2018. He has played an intricate role in the development of therapeutic treatments, products and programs from the research stage to market and commercialization. Mr. Jackman 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. He 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, 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 of Science in Management, and a Bachelor of Engineering in 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 began working for Alzamend on a part-time basis on December 15, 2018. He 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., formerly known as Digital Power Corporation (NYSE: DPW) and (“DPW”) and serves on the Board of Directors and Chairman of the Audit Committee of Verb Technology Company, Inc. (NASDAQ: VERB). 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 serve as our CFO.

**Henry C. W. Nisser**

Mr. Nisser began working for Alzamend on a part-time basis on May 1, 2019. From October 31, 2011 through April 26, 2019, Mr. Nisser was an associate and subsequently a partner with Sichenzia Ross Ference LLP (“SRF”), a law firm based in New York City. While with SRF, his practice was concentrated in national and international corporate law, with a particular focus on U.S. securities compliance, public as well as private M&A, equity and debt financings and corporate governance. Mr. Nisser drafted and negotiated a variety of agreements related to reorganizations, share and asset purchases, indentures, public and private offerings, tender offers and going private transactions. Mr. Nisser also represented clients’ special committees established to evaluate M&A transactions and advised such committees’ members with respect to their fiduciary duties. Mr. Nisser is fluent in French and Swedish as well as conversant in Italian. Mr. Nisser received his B.A. from Connecticut College in 1992, where he majored in International Relations and Economics. He received his LLB from the University of Buckingham School of Law in 1999.

**Milton C. Ault, III**

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

**Philip E. Mansour**

Mr. Mansour has served as a director and as the President and Chief Executive Officer of Avalanche since May 2014. Additionally, Mr. Mansour has provided executive coaching services. Mr. Mansour was the CEO of Alzamend from 2016 through 2018. 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. He has also served as 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 us. We believe that Mr. Mansour’s business background demonstrates he has the qualifications to serve as one of our directors.

**William B. Horne.**

Mr. Horne has served as director for Alzamend Neuro since June 1, 2016. Mr. Horne served as the Chief Financial Officer from June 2016 through December 2018. Mr. Horne has been 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 and Chief Financial Officer of Avalanche, a publicly traded company.

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 gives 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 our 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, we are 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 five 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. 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 of Title 11 of the United States Code (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

Compensation of our three most highly paid executive officers or directors for the year ended April 30, 2019 was as follows:

Name and Principal Position	Cash	Other	Total
	Compensation (\$)	Compensation (\$) (1)	Compensation (\$)
Stephan Jackman, Chief Executive Officer	\$ 50,000	\$ 3,317,557	\$ 3,367,557
Kenneth S. Cragun, Chief Financial Officer	\$ 20,000	\$ 1,147,549	\$ 1,167,549

(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 any other officers or directors outside of the MSA with Avalanche. The services of the two former officers and Executive Chairman of our 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, 2018, with Avalanche having initially received \$40,000 per month and, beginning February 2017, receiving \$20,000 per month for the remainder of 2017. During the years ended April 30, 2019 and 2018, we recognized \$160,000 and \$240,000, respectively, in management fees. At April 30, 2019 and April 30, 2018, \$75,000 and \$3,000, respectively, was included within related party payable on our balance sheet. The MSA was terminated as of December 31, 2018.

### Employment agreement with Stephan Jackman

On November 18, 2018, we entered into an offer letter with Stephan Jackman to serve as our Chief Executive Officer. Based on the terms set forth in the offer letter, we intend to enter into a four-year employment agreement with Mr. Jackman. For his services, Mr. Jackman will be paid a base salary of \$150,000 per annum, which sum will be increased to \$180,000 upon the approval of the FDA IND application for LiProSal<sup>TM</sup>, and to \$225,000 upon the approval of the FDA IND application for CAO22W. In addition, Mr. Jackman shall be eligible to receive an annual cash bonus equal to a percentage of his annual base salary based on achievement of applicable performance goals determined by the Board.

Further, Mr. Jackman received an option to purchase 5,000,000 shares of Common Stock exercisable for a period of ten (10) years from November 16, 2018, at a per share price of \$1.00, which option will vest as follows:

- Three million (3,000,000) shares of Common Stock shall vest ratably over 48 months beginning on November 16, 2018;
- One million (1,000,000) shares of Common Stock shall vest upon approval of an NDA for LiProSal<sup>TM</sup> by the FDA within 36 months from November 1, 2018; and
- One million (1,000,000) shares of Common Stock shall vest upon approval of an NDA for CAO2W by the FDA within 48 months from November 1, 2018.

### Employment agreement with Ken Cragun

On November 30, 2018, we entered into an offer letter with Kenneth Cragun to serve as our Chief Financial Officer. Based on the terms set forth in the offer letter, we intend to enter into a four-year employment agreement Mr. Cragun. For his services, Mr. Cragun will be paid a base salary of \$60,000 per annum, which sum will be increased to \$120,000 upon the approval of a listing application submitted on behalf of our company to have our shares of Common Stock listed on a national securities exchange. In addition, Mr. Cragun shall be eligible to receive an annual cash bonus equal to a percentage of his annual base salary based on achievement of applicable performance goals determined by the Board.

Further, Mr. Cragun received an option to purchase 1,500,000 shares of Common Stock exercisable for a period of ten (10) years from December 15, 2018, at a per share price of \$1.00. The option will vest ratably over 48 months beginning on December 15, 2018; however, 500,000 shares of Common Stock will vest immediately upon the approval of a listing application submitted on behalf of our company to have our shares of Common Stock listed on a national securities exchange.

#### **Employment agreement with Henry Nisser**

On May 20, 2019, we entered into a four-year employment agreement having an effective date of May 1, 2019, with Henry Nisser to serve our Executive Vice President and General Counsel. For his services, Mr. Nisser will be paid a base salary of \$50,000 per annum. In addition, Mr. Nisser shall be eligible to receive an annual cash bonus equal to a percentage of his annual base salary based on achievement of applicable performance goals determined by the Board.

Further, Mr. Nisser shall be entitled to receive an option an option to purchase 1,250,000 shares of Common Stock exercisable for a period of five (5) years at a per share exercise price of \$1.50. The shares of Common Stock underlying the option shall vest ratably over 48 months beginning on June 1, 2019.

#### **Consulting Agreement with Dr. Chuanhai Cao**

In December 2017, we entered into a five-year consulting agreement with Dr. Chuanhai Cao to support the design and incremental work to obtain FDA approval for CAO22W. The agreement included an initial payment of \$6,000 and monthly payments of \$3,000 per month plus 500,000 options at \$1.00 per share that vest ratably over the term of the agreement.

#### **Scientific Advisory Board Agreements**

We entered into consulting agreements with Dr. Thomas Wisniewski and Dr. Eric McDade and February 1, 2019 and May 1, 2019, respectively. The annual cash compensation under the consulting agreements is \$12,000 per committee member and options to purchase 50,000 shares at \$1.00 per share with a three-year life, vesting over two years.

Dr. Eric McDade is a cognitive neurologist actively involved in the field of Alzheimer disease treatment. Dr. McDade is the Principal Investigator at the DIAN Expanded Registry and Associate Professor at the Washington University School of Medicine. He received his Doctor of Osteopath, Medicine from the Chicago College of Osteopathic Medicine.

Dr. Thomas Wisniewski is the Director of the Center for Cognitive Neurology at NYU Langone's Alzheimer's Disease Center. Dr. Wisniewski received his MD from the University of London.

#### **ITEM 4. SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS**

The following table shows the beneficial ownership of our Common Stock as of July 31, 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 July 31, 2019, there were 61,906,132 shares of Common Stock issued and outstanding and 750,000 shares of Series A Convertible 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.

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>Directors and Officers</b>	<b>Number of shares of Common Stock Beneficially Owned</b>	<b>Percentage of Shares Beneficially Owned</b>
Philip E. Mansour (1)	2,500,000	3.88%
Milton C. Ault, III (2)(3)(4)	55,000,000	51.45%
William B. Horne (1)	2,500,000	3.88%
Stephan Jackman (5)	625,000	1.00%
Kenneth S. Cragun (5)	281,250	0.45%
Henry Nisser (5)	130,208	0.21%
All directors and named executive officers as a group (6 persons)	61,036,458	54.04%
<b>Greater than 10% Beneficial Owners:</b>		
MCKEA Holdings, LLC (3)	37,500,000	37.72%
Ault Life Sciences Fund, LLC (4)	15,000,000	22.42%

1) Consists of options to purchase 2,500,000 shares of Common Stock that are exercisable within 60 days of July 31, 2019.

(2) Includes options to purchase 2,500,000 shares of Common Stock that are exercisable within 60 days of July 31, 2019.

(3) Includes 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) Includes 10,000,000 shares of Common Stock and warrants to purchase 5,000,000 shares of Common Stock held by Ault Life Sciences Fund, LLC that are exercisable within 60 days of July 31, 2019. The control person of Ault Life Sciences Fund, LLC is Mr. Ault, the Executive Chairman of our company.

(5) Represents options to purchase shares of Common Stock that are exercisable within 60 days of July 31, 2019. Mr. Nisser's address is 100 Park Avenue, Suite 1658, New York, NY 10017.

#### **ITEM 5. INTEREST OF MANAGEMENT AND OTHERS IN CERTAIN TRANSACTIONS**

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

As of April 30, 2016, we 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 our 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, Executive Chairman of our Board.

On May 1, 2016, we 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. We 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, 2019 and 2018, we recognized \$160,000 and \$240,000, respectively, in management fees. At April 30, 2019 and April 30, 2018, \$75,000 and \$3,000, respectively, was included within related party payable on our balance sheet. The MSA expired 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 us 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 us 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, 2019 and 2018, to MCKEA and our officers for reimbursement of expenses paid and incurred by these related parties was \$6,736 and \$6,636, respectively. The amounts are included within related party payable on our 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 our balance sheet (See Note 11).

On April 10, 2018, Avalanche, issued the AVLP Note to evidence our loan of up to \$995,500 for the 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. During the year ended April 30, 2019, we provided loans to Avalanche in the principal amount of \$792,085, of which \$558,000 was repaid. The balance outstanding on the AVLP Note as of April 30, 2019 was \$205,915.

On April 30, 2019, we entered into a securities purchase agreement for the purchase of 10,000,000 shares of Common Stock for a total purchase price of \$15,000,000, or \$1.50 per share with 5,000,000 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance. The total purchase price of \$15,000,000 was in the form of a note receivable with a 12-month term from Ault Life Sciences Fund, LLC, a related party. The control person of Ault Life Sciences Fund, LLC is Mr. Ault, the Executive Chairman of our company.

To the best of our knowledge, from inception to our most recent fiscal year end on April 30, 2019, 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 sheets of Alzamend Neuro, Inc. (the "Company") as of April 30, 2019 and 2018, and the related statements of operations, changes in stockholders' equity and cash flows for the years 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 as of April 30, 2019 and 2018, and the results of its operations and its cash flows for the years 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, 2019, and does not have sufficient working capital at April 30, 2019 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ SQUAR MILNER LLP

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

San Diego, California  
August 28, 2019

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

	<b>April 30, 2019</b>	<b>April 30, 2018</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash	\$ 42,606	\$ 545,001
Note receivable, related party, net	205,915	403,333
Prepaid expenses and other current assets	1,252,396	1,467,685
<b>TOTAL CURRENT ASSETS</b>	<b>1,500,917</b>	<b>2,416,019</b>
<b>TOTAL ASSETS</b>	<b>\$ 1,500,917</b>	<b>\$ 2,416,019</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 1,104,669	\$ 90,088
Related party payable	79,333	6,636
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,184,002</b>	<b>96,724</b>
<b>COMMITMENTS AND CONTINGENCIES (Note 13)</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Convertible Preferred stock, \$0.0001 par value: 10,000,000 shares authorized; Series A Convertible Preferred Stock, \$0.0001 stated value per share, 1,360,000 shares designated; 750,000 shares issued and outstanding as of April 30, 2019 and 2018, respectively	75	75
Common stock, \$0.0001 par value: 300,000,000 shares authorized; 61,878,465 and 49,493,196 shares issued and outstanding as of April 30, 2019 and 2018, respectively	6,188	4,949
Additional paid-in capital	22,686,285	4,827,408
Note receivable – related party for common stock	(15,000,000)	-
Accumulated deficit	(7,375,633)	(2,513,137)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>316,915</b>	<b>2,319,295</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 1,500,917</b>	<b>\$ 2,416,019</b>

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>2019</b>	<b>2018</b>
<b>OPERATING EXPENSES</b>		
Research and development	\$ 3,700,083	\$ 323,403
General and administrative	1,308,800	575,027
Total operating expenses	5,008,883	898,430
<b>Loss from operations</b>	(5,008,883)	(898,430)
<b>OTHER INCOME (EXPENSE), NET</b>		
Interest income - related party	146,387	7,341
Interest expense	-	(30,259)
Interest expense - debt discount	-	(10,315)
<b>Total other income (expense), net</b>	146,387	(33,233)
<b>NET LOSS</b>	\$ (4,862,496)	\$ (931,663)
<b>Basic and diluted net loss per common share</b>	\$ (0.08)	\$ (0.02)
<b>Basic and diluted weighted average common shares outstanding</b>	58,843,040	45,389,196

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>2019</b>	<b>2018</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,862,496)	\$ (931,663)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest expense -- debt discount	-	10,315
Legal expense -- debt discount	-	1,809
Accretion of original issue discount on notes receivable – related party	(36,667)	(3,333)
Issuance of common stock for license fees	2,227,923	218,417
Stock-based compensation to employees and consultants	396,170	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	215,289	(1,415,368)
Deferred offering costs	-	75,000
Accounts payable and accrued expenses	1,014,581	(6,877)
<b>Net cash used in operating activities</b>	<b>(1,045,200)</b>	<b>(2,051,700)</b>
<b>Cash flows from investing activities:</b>		
Loans to related party	(558,000)	(840,000)
Proceeds from repayment of loans to related party	792,085	440,000
<b>Net cash provided by (used in) investing activities</b>	<b>234,085</b>	<b>(400,000)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	236,023	3,615,236
Advances from related party payable	72,697	(259,411)
Proceeds from notes payable, related party	-	138,500
Payments on notes payable	-	(75,000)
Payments on notes payable, related party	-	(427,600)
<b>Net cash provided by financing activities</b>	<b>308,720</b>	<b>2,991,725</b>
<b>Net (decrease) increase in cash</b>	<b>(502,395)</b>	<b>540,025</b>
Cash at beginning of period	545,001	4,976
Cash at end of period	\$ 42,606	\$ 545,001
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the period for interest	\$ -	\$ 30,569
<b>Non-cash financing activities:</b>		
Fair value of warrants issued in connection with promissory note	\$ -	\$ 2,235
Issuance of notes payable from related party in payment of accrued expenses	\$ -	\$ 29,000
Issuance of common stock upon conversion of convertible preferred stock	\$ -	\$ 1,220
Issuance of common stock for note receivable – related party	\$ 15,000,000	\$ -

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

**ALZAMEND NEURO, INC.**  
**Statements of Changes in Stockholders' Equity**  
**Years Ended April 30, 2019 and April 30, 2018**

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable - Related Party for Common Stock	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
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	750,000	75	49,493,196	4,949	4,827,408	-	(2,513,137)	2,319,295
Issuance of common stock	-	-	157,346	16	236,007	-	-	236,023
Issuance of common stock to related party	-	-	10,000,000	1,000	14,999,000	(15,000,000)	-	-
Stock-based compensation to employees and consultants	-	-	-	-	396,170	-	-	396,170
Issuance of common stock for license fees	-	-	2,227,923	223	2,227,700	-	-	2,227,923
Net loss	-	-	-	-	-	-	(4,862,496)	(4,862,496)
BALANCES, April 30, 2019	<u>750,000</u>	<u>\$ 75</u>	<u>61,878,465</u>	<u>\$ 6,188</u>	<u>\$ 22,686,285</u>	<u>\$ (15,000,000)</u>	<u>\$ (7,375,633)</u>	<u>\$ 316,915</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 disease (“Alzheimer’s” or “AD”). The Company has licensed an immunotherapy vaccine peptide that works both as a treatment and vaccine against Alzheimer’s and an ionic cocrystal of lithium to mitigate extreme agitation and forestall other deterioration as displayed by patients with up to moderate AD and possibly other neurodegenerative diseases (collectively, 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; further, their respective exercise prices were increased by a factor of four as of the foregoing date. 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 authorized capital and par value per share of the Company’s Common Stock was not affected by the Reverse Stock Split.

The Company is devoting substantially all 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, 2019, the Company had cash of \$42,606 and an accumulated deficit of \$7,375,633. The Company has incurred recurring losses and for the year ended April 30, 2019, such losses totaled \$4,862,496. In the past, the Company has financed its operations principally through issuances of promissory notes and equity securities. During the year ended April 30, 2019, the Company continued to 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, the Company believes that our cash at April 30, 2019, is 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. Our 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, 2019 and 2018, the Company had no cash equivalents.

## Fair Value of Financial Instruments

Our 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.

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, 2019, 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.

Our 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. The Company has included 7,500,000 stock options, with an exercise price of \$0.0004, in its loss per share calculation for the years ended April 30, 2019 and 2018.

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,	
	2019	2018
Series A convertible preferred stock	15,000,000	15,000,000
Stock options (1)	8,210,000	-
Warrants	5,584,172	43,000
	<u>28,794,172</u>	<u>15,043,000</u>

(1) The Company has excluded 7,500,000 stock options, with an exercise price of \$0.0004, from its anti-dilutive securities.

## 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 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. Upon adoption of this subtopic, the Company expects the impact to be immaterial on its financial position, results of operations, cash flows, or financial statement disclosures as our only lease, which is related to office space, has a term of less than 12 months.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)* (“ASU 2017-11”). ASU 2017-11 consists of two parts. The amendments in Part I of this update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (“EPS”) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common stockholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, *Debt—Debt with Conversion and Other Options*), including related EPS guidance (in Topic 260). The amendments in Part II of this update re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments in Part II of this update do not require any transition guidance because those amendments do not have an accounting effect. The Company chose to early adopt ASU 2017-11 for the fiscal year ended April 30, 2019. The early adoption allows the Company to reduce the cost and complexity of accounting for financial instruments that, due to down round provisions, would otherwise require fair value measurement each reporting period and eliminate the corresponding impact and unnecessary volatility in reported earnings created by the revaluation when the Company’s share value changes.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, (“ASU 2018-07”). ASU 2018-07 simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under ASU 2018-07, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after Dec. 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. The Company is currently evaluating the impact of adopting this standard on its consolidated financial statements and related disclosures but does not expect it to have a material impact.

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, Avalanche International Corp., a related party (“Avalanche”), issued a promissory note (the “AVLP Note”) to the Company pursuant to which the Company agreed to provide Avalanche a loan of up to \$995,500 for the 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 the year ended April 30, 2019, the Company provided loans to Avalanche in the principal amount of \$558,000 and received payments of \$792,085. As of April 30, 2019, the balance of the loan receivable from Avalanche was \$205,915.

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 \$90,500 was amortized as interest income through the maturity date. During the year ended April 30, 2019, the Company recorded \$87,167 of interest income for the discount accretion and recorded contractual interest income from the stated interest rate of \$59,220. 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.

On April 30, 2019, the Company and Ault Life Sciences Fund, LLC (“ALSF”) entered into a securities purchase agreement (the “SPA”) for the purchase of 10,000,000 shares of Common Stock for a total purchase price of \$15,000,000, or \$1.50 per share with 5,000,000 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance. The total purchase price of \$15,000,000 was in the form of a non-interest bearing note receivable with a 12-month term from ALSF, a related party. The note is secured by a pledge of the purchased shares. As the note receivable from ALSF is related to the issuance of common stock, it is recorded as an offset to additional paid-in capital.

#### 5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are as follows:

	April 30, 2019	April 30, 2018
Prepaid assets	\$ 1,172,957	\$ 1,446,667
Interest receivable	63,229	4,008
Other receivables	16,210	17,010
Total prepaid expenses and other current assets	<u>\$ 1,252,396</u>	<u>\$ 1,467,685</u>

##### *Spartan 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. As of April 30, 2019 the unamortized balance under this agreement was \$1,026,667, which is included in prepaid expenses and other current assets.



## 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, 2019 and 2018, 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.

	<u>April 30, 2019</u>	<u>April 30, 2018</u>
Deferred income tax asset:		
Net operating loss carryover	\$ 1,541,317	\$ 517,972
Other temporary differences	120,739	7,637
Total deferred tax asset	<u>1,662,056</u>	<u>525,609</u>
Valuation allowance	(1,662,056)	(525,609)
Deferred income tax asset, net of allowance	<u>\$ -</u>	<u>\$ -</u>

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

	<u>For the Year Ended April 30,</u>	
	<u>2019</u>	<u>2018</u>
Federal and State		
Current	\$ -	\$ -
Deferred	(1,662,056)	(525,609)
Valuation allowance	<u>1,662,056</u>	<u>525,609</u>
Income tax provision (benefit)	<u>\$ -</u>	<u>\$ -</u>

On December 22, 2017, the U.S. Congress 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, 2019 and 2018, the Company did not recognize income tax expense. Our effective tax rate was 0% for the years ended April 30, 2019 and 2018. 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 to income tax expense is as follows:

	<u>For the Year Ended April 30,</u>	
	<u>2019</u>	<u>2018</u>
Tax benefit at U.S. Federal statutory tax rate	-21.0%	-29.7%
Increase (decrease) in tax rate resulting from:		
Allowance against deferred tax assets	20.9%	-1.0%
Nondeductible meals & entertainment expense and other	0.1%	0.1%
Taxes in respect of prior years	-	-
Changes in federal tax rate	-	30.6%
Effective tax rate	<u>0.0%</u>	<u>0.0%</u>

At April 30, 2019, the Company had total domestic Federal net operating loss carryovers of approximately \$7,185,129 available to offset future taxable income. Federal net operating loss carryovers (“NOLs”) expire beginning in 2026. The Company has not filed its 2016 through 2019 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, 2019 the valuation allowance has increased by \$1,136,447.

The 2016 through 2019 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 12,500,000 shares of the Company's Common Stock to be offered to the Company's directors, officers, employees, and consultants. On March 1, 2019 the Company's shareholders approved an additional 7,500,000 shares to be available for issuance under the plan. 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.

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, 2019 and 2018, and changes during the years ended are as follows:

	<b>Outstanding Options</b>				<b>Aggregate Intrinsic Value</b>
	<b>Shares Available for Grant</b>	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (years)</b>	
Balance at April 30, 2017	4,875,000	7,625,000	\$ 0.0004	9.00	\$ 1,296,250
Forfeited	125,000	(125,000)	\$ 0.0004		
Balance at April 30, 2018	5,000,000	7,500,000	\$ 0.0004	8.00	\$ 7,497,000
Increase to plan shares	7,500,000				
Options granted	(8,210,000)	8,210,000	\$ 1.0000		
Balance at April 30, 2019	4,290,000	15,710,000	\$ 0.5228	7.51	\$ 15,352,000
Options vested and expected to vest at April 30, 2019		13,710,000	\$ 0.4532	8.16	\$ 14,352,000
Options exercisable at April 30, 2019		8,045,415	\$ 0.0682	7.17	\$ 11,519,708

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 years ended April 30, 2019 and 2018.

### ***Stock options granted to employees and consultants***

During the year ended April 30, 2018, 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. The estimated fair value of stock options granted to employees and consultants during the year ended April, 2019, were calculated using the Black-Scholes option-pricing model using the following assumptions:

	<b>For the Year Ended April 30, 2019</b>
Expected term (in years)	3.00 - 6.25
Volatility	83.40%
Risk-free interest rate	2.50% - 2.95%
Dividend yield	--

*Expected Term:* The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

*Expected Volatility:* The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-Free Interest Rate:* The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

*Expected Dividend:* The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

### ***Performance-contingent stock options granted to employee***

In November 2018, the Board of Directors granted 2,000,000 performance-contingent options to the Chief Executive Officer. These options have an exercise price of \$1.00 per share.

These options have two separate performance triggers for vesting based upon our therapies achieving certain FDA approval milestones within a specified timeframe. By definition, the performance condition in these options can only be achieved after the performance condition of FDA approval has been achieved. As such, the requisite service period is based on the estimated period over which the market condition can be achieved. When a performance goal is deemed to be probable of achievement, time-based vesting and recognition of stock-based compensation expense commences. In the event any the milestones are not achieved by the specified timelines, such vesting award will terminate and no longer be exercisable with respect to that portion of the shares. The maximum potential expense associated with the performance-contingent awards is \$1.2 million of general and administrative expense if all of the performance conditions are achieved as stated in the option agreement. Due to the significant risks and uncertainties associated with FDA approvals, through April 30, 2019, the Company believes that the achievement of the requisite performance conditions is not probable and, as a result, no compensation cost has been recognized for these awards.

### ***Stock issued for license fees***

Pursuant to the terms of the License Agreement, during the years ended April 30, 2019 and 2018, the Company issued 2,227,923 and 214,967 shares of its Common Stock and recognized \$2,227,923 and \$218,417, respectively, in license fees.

### Stock-based compensation expense

The Company's results of operations include expenses relating to stock-based compensation as follows:

	For the Year Ended April 30,	
	2019	2018
Research and development	\$ 2,227,923	\$ 218,417
General and administrative	396,170	-
Total	<u>\$ 2,624,093</u>	<u>\$ 218,417</u>

As of April 30, 2019, total unamortized stock-based compensation expense related to unvested employee and non-employee awards that are expected to vest was \$4.1 million. The weighted-average period over which such stock-based compensation expense will be recognized is approximately 3.6 years.

### 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. ("DPW"), a related party (See Note 11).

On March 10, 2019, the Company issued warrants to purchase 500,000 shares of Common Stock at an exercise price equal to \$1.00 per share of Common Stock in connection with entering into a two-year advisory agreement with a consultant related to identifying sources of capital for the Company. The warrants vest over five years. The grant date fair value of the warrants was \$217,448 and will be expensed over the term of the consulting agreement. The estimated fair value of warrants granted to the consulting during the year ended April, 2019, was calculated using the Black-Scholes option-pricing model using the following assumptions:

Warrants	For the Year Ended April 30, 2019
Expected term (in years)	2.50
Volatility	69.35%
Risk-free interest rate	2.53%
Dividend yield	--

*Expected Term:* The expected term represents the period that the warrants granted are expected to be outstanding.

*Expected Volatility:* The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-Free Interest Rate:* The Company based the risk-free interest rate over the expected term of the warrants based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

*Expected Dividend:* The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

On March 20, 2019, the Company issued 78,672 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance in connection with a securities purchase agreements for the purchase of 157,346 shares of Common Stock for a total purchase price of \$236,023, or \$1.50 per share.

On April 30, 2019, the Company issued 5,000,000 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance to ALSF, a related party, in connection with a securities purchase agreement ("SPA") for the purchase of 10,000,000 shares of Common Stock for a total purchase price of \$15,000,000, or \$1.50 per share. The terms of the warrant agreement include full ratchet anti-dilution protection.

The following table summarizes information about Common Stock warrants outstanding at April 30, 2019:

Outstanding				Exercisable			
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price		
\$1.20	5,500	1.42	\$ 1.20	5,500	\$ 1.20		
\$1.00	500,000	4.86	\$ 1.00	--	--		
\$3.00	5,078,672	5.00	\$ 3.00	78,672	\$ 3.00		
<b>\$1.20 - \$3.00</b>	<b>5,584,172</b>	<b>4.98</b>	<b>\$ 1.27</b>	<b>84,172</b>	<b>\$ 2.88</b>		

## 9. OTHER RELATED PARTY TRANSACTIONS

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, 2019 and 2018, the Company recognized \$160,000 and \$240,000, respectively, in management fees. At April 30, 2019 and April 30, 2018, \$75,000 and \$3,000, respectively, was included within related party payable on the Company’s balance sheet. The MSA expired as of 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 Confidential Private Placement Memorandum dated August 17, 2017 (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, 2019 and 2018, to MCKEA and the Company’s officers for reimbursement of expenses paid and incurred by these related parties was \$6,736 and \$6,636, respectively. The amounts are included within related party payable on the Company’s balance sheet.

## 10. NOTES PAYABLE

During January 2017, the Company entered into a promissory note to a third party 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 year ended April 30, 2018, interest expense of \$3,618 was recorded from the debt discount amortization. The promissory note accrued interest at 15% per year and during the year ended April 30, 2018, the Company recorded \$16,838 in interest. This loan was repaid during the year ended April 30, 2018. At April 30, 2019 and 2018, the Company had no outstanding third-party borrowings.

## 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, 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, 2019 and 2018, interest expense of nil and \$6,271, respectively, was recorded from the debt discount amortization. This promissory note accrued interest at 15% per year and during the years ended April 30, 2019 and 2018, the Company recorded nil and \$6,272, respectively, in interest. The Company repaid this loan during the year ended April 30, 2018.

On October 1, 2017, the Company issued a promissory note in the principal amount of \$47,520 to 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. During the year ended April 30, 2018, the Company repaid the outstanding balance to DPW.

## 12. EQUITY TRANSACTIONS

The Company is authorized to issue 10,000,000 shares of Preferred Stock \$0.0001 par value. The Board of Directors has designated 1,360,000 shares as Series A Convertible Preferred Stock (the "Series A Preferred Shares"). The rights, preferences, privileges and restrictions on the remaining authorized 8,640,000 shares of Preferred Stock have not been determined. The Company's Board of Directors is authorized to create a new series of preferred shares and determine the number of shares, as well as the rights, preferences, privileges and restrictions granted to or imposed upon any series of preferred shares. As of April 30, 2019, there were 750,000 shares of Series A Preferred Shares and no other shares of Preferred Stock issued or outstanding.

### *Series A Preferred Stock*

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.

### *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.

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 of South Florida (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 University of South Florida Research Foundation, Inc. (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, 2018, the Company issued 214,967 shares of its Common Stock and recognized \$218,417 in license fees pursuant to the License Agreement. During the year ended April 30, 2019, the Company issued 2,227,923 shares of its Common Stock and recognized \$2,227,923 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 also received shares of the Company's Common Stock equal to five percent (5%) of the total number of issued and outstanding shares outstanding as the Company has received a total of \$5 million in cash in exchange for the Company's equity securities.

Between October 19, 2017 and December 29, 2017, the Company entered into subscription agreements for the purchase of 419.45 units at \$10,000 for each unit purchased. Each unit consisted of 10,000 shares of Common Stock. In aggregate, the 419.45 units represented 4,194,500 shares of Common Stock for an aggregate purchase price of \$4,194,500, or \$1.00 per share, pursuant to the terms of a Private Placement Memorandum dated August 17, 2017 (the "PPM"). In conjunction with the 2017 PPM, the Company incurred \$419,450 in placement fees and \$93,523 in legal and filing fees, resulting in net proceeds to the Company of \$3,681,528 (the "2017 Offering").

During the year ended April 30, 2018, the Company received notices of conversion from three investors that had purchased 610,000 shares of Series A Preferred Stock. The Series A Preferred Stock was converted into 12,200,000 shares of Common Stock.

On March 20, 2019, the Company entered into securities purchase agreements for the purchase of 157,346 shares of Common Stock for a total purchase price of \$236,023, or \$1.50 per share with 78,672 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance. The purchase price of \$236,023 was paid in cash.

On April 30, 2019, the Company and ALSF entered into a SPA for the purchase of 10,000,000 shares of Common Stock for a total purchase price of \$15,000,000, or \$1.50 per share with 5,000,000 warrants with a 5-year life and an exercise price of \$3.00 per share and vesting upon issuance. The total purchase price of \$15,000,000 was in the form of a non-interest bearing note receivable with a 12-month term from ALSF, a related party. The note is secured by a pledge of the purchased shares. Pursuant to the SPA, ALSF is entitled to full ratchet anti-dilution protection, most-favored nation status, denying the Company the right to enter into a variable rate transaction absent its consent, a right to participate in any future financing the Company may consummate and to have all the shares of Common Stock to which it is entitled under the SPA registered under the Securities Act within 180 days of the final closing of an initial public offering.

#### *Placement Agreement*

In connection with the 2017 Offering, the Company agreed with Spartan Capital Securities, LLC ("Spartan"), the placement agent in the 2017 Offering, as follows:

#### Use of Proceeds

The Company will apply the net proceeds from the Offering to include the retention of an 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. COMMITMENTS AND CONTINGENCIES**

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 Licensor is entitled to receive that number of shares of our 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 our equity securities. As of April 30, 2019 we had issued 3,601,809 shares to the Licensor in full satisfaction of this additional licensing fee. 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	Upon IND application filing	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 April 30, 2019. If the Company fails to meet a milestone by its specified date, the Licensor may terminate the License Agreement.

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 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 owned by 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.



On July 2, 2018, the Company obtained two royalty-bearing, exclusive worldwide licenses from the Licensor 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. 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™ 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 March 31, 2019. 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 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

None of these milestones was met as of April 30, 2019. If the Company fails to meet a milestone by its specified date, the Licensor may terminate the License Agreement.

#### **14. SUBSEQUENT EVENTS**

In accordance with FASB ASC 855-10, the Company has analyzed its operations subsequent to April 30, 2019 and has determined that it does not have any material subsequent events to disclose in these financial statements except for the following.

Between June 25, 2019 and August 15, 2019, the Company entered into subscription agreements for the purchase of 646,433 units at \$1.50 for each unit purchased pursuant to its 2019 private offering (the "2019 Offering"). Each unit consists of one (1) share of Common Stock and one (1) warrant to purchase one half (0.5) share of Common Stock. In aggregate, the 646,433 units represents 646,433 shares of Common Stock and 323,216 warrants with an exercise price of \$3.00 per share for an aggregate purchase price of \$969,650, or \$1.50 per share. The 2019 Offering is being conducted pursuant to the terms of a Confidential Private Placement Memorandum dated June 12, 2019 (the "2019 PPM"). As of August 15, 2019, in conjunction with the 2019 PPM, the Company incurred \$145,448 in placement fees, resulting in net proceeds to the Company of \$824,202.

#### **2019 Placement Agreement**

Pursuant to the 2019 Placement Agreement effective as of June 10, 2019 entered into in connection with the 2019 PPM, the Company has agreed with the Placement Agent to certain cash compensation payable to the Placement Agent and, without limitation, to the following:

##### Placement Agent Compensation:

Upon the initial closing of the 2019 Offering the Company must pay to the Placement Agent a non-refundable fee of Twenty-Five Thousand Dollars (\$25,000) and issue to the Placement Agent 500,000 shares of Common Stock.

Further, the Company has agreed to issue to the Placement Agent warrants to purchase a number of shares of Common Stock (the "Placement Agent Warrants") equal to ten percent (10%) of the number of shares of Common Stock sold in the 2019 Offering. The Placement Agent Warrants shall be exercisable for a period of five (5) years after their date of issuance, shall have an exercise price of \$1.75 per share and shall contain provisions pertaining to cashless exercise, standard anti-dilution protection and piggyback registration rights.

Use of Proceeds:

The Company will apply the net proceeds from the Offering primarily: (i) for licensing and other fees to the University and the Byrd Institute; (ii) to pay certain fees to the FDA; (iii) to pay for third-party research; (iv) to pay certain marketing-related fees, and (v) for working capital.

Incurrence of Debt:

During the two (2) years following the final Closing, the Company will not, without the prior written consent of the Placement Agent, incur indebtedness for borrowed money in an aggregate amount in excess of \$250,000.

Additional Shares Issuable to the Placement Agent, its Affiliates and the Investors in this Offering

The Company has agreed to take certain actions within prescribed time periods. If the Company fails to do so on a timely basis, the Company has agreed to issue to the Placement Agent, its Affiliates and the investors in the 2019 Offering a significant number of additional shares of Common Stock.

Future Sales of Securities and Conversion of the Series A Preferred Stock

During the period commencing on the final Closing and ending two years thereafter, provided that no Qualified Financing (as defined below) has occurred, if (i) the Company issues any shares of Common Stock or Common Stock equivalents at a per share price below \$1.50 absent the Placement Agent's consent, or (ii) any holder of the Company's Series A Preferred Stock elects to convert such shares into Common Stock, then upon any such issuance or conversion, as the case may be, the Placement Agent, its Affiliates and the Investors in this Offering will be entitled to receive a significant number of additional shares of Common Stock (this provision can thus be deemed the functional equivalent of weighted average anti-dilution protection). For purposes of the 2019 Placement Agreement, a "Qualified Financing" means the sale of equity securities by us in a single transaction or a series of related transactions registered under the Securities Act resulting in gross proceeds to us of not less than \$25,000,000.

In addition, during the period commencing on the final Closing and ending two years thereafter, the Company has agreed not to enter into any transactions with Milton C. Ault, our chairman of the board and principal stockholder or any Affiliate (as defined in Rule 405 of the Securities Act) thereof absent the Placement Agent's consent. Notwithstanding the foregoing, the Placement Agent has consented to our potential entry into an agreement whereby the Company would issue to an Affiliate of Mr. Ault 10,000,000 shares of Common Stock on terms substantially identical to those of the 2019 Offering.

Failure to File Reports under the Securities Act

In the event that the Company does not file its annual or semiannual reports with the Commission on a timely basis, then the Placement Agent will have the right to designate a replacement for one of our members of our Board for a period of one (1) year following any such failure to file a periodic report on a timely basis, provided that neither Mr. Ault nor William B. Horne shall be subject to this provision.

Employment Agreement with the Chief Executive Officer:

Upon or before the initial Closing of the 2019 Offering, the Company shall have entered into an employment agreement with Stephan Jackman having a term of at least two (2) years.

Corporate Governance:

During the period commencing on the final closing of the 2019 Offering and ending at such time as the Common Stock is listed on a national securities exchange, the Placement Agent will have the right to designate one member of our Board.

Uplisting Agreement:

Pursuant to the Uplisting Agreement effective as of June 10, 2019, the Company has agreed with the Placement Agent as follows:

The Company will engage the Placement Agent as an advisor (in such capacity, the "Advisor") to, at our request, provide advisory services (the "Services") to us in connection with a potential public offering (an "IPO"). The Company expects that any such Services rendered would consist principally of advising us on how to properly develop and implement strategies that would enhance our ability to successfully complete an IPO and in connection therewith obtain a listing on a national securities exchange, provided that the Company meets any such exchange's listing criteria at the applicable time as well as introduce us to appropriate underwriters that would lead or conduct any such IPO.

According to the Uplisting Agreement, the Company will, whether the Company requests its assistance or not, be obligated to issue to the Advisor Five Hundred Thousand (500,000) shares of Common Stock as well as make a cash payment to the Advisor in the amount of \$475,000 once the Company has raised no less than \$1,000,000 in gross proceeds in the 2019 Offering and, in the event that the Company successfully consummates an IPO with an underwriter introduced to us by the Advisor, pay the Advisor a fee equal to two percent (2%) of the gross proceeds raised in the IPO.

If prior to a Qualified Financing the Company issues any shares of Common Stock or Common Stock equivalents at a per share price below \$1.50 absent the Advisor's consent, then upon any such issuance, the Advisor will be entitled to receive a significant number of additional shares of Common Stock (this provision can, like its counterpart in the 2019 Placement Agreement described above, thus be deemed the functional equivalent of weighted average anti-dilution protection).

In the event that the Company engages in what the Uplisting Agreement refers to as an "Alternative Transaction" during the term of such agreement or for a period of two (2) years thereafter, the Company will be obligated to pay to the Advisor a fee in cash equal to three percent (3%) of the amount of the consideration paid or received by us and/or our stockholders in the Alternative Transaction. For purposes of the Uplisting Agreement, an "Alternative Transaction" means a business combination, including, any merger, acquisition or sale of stock or assets (whether the Company is the acquiring or the acquired entity), joint venture, strategic alliance or other similar transaction, and shall extend to any subsidiary of ours on the same terms as will be applicable to us.

The term of the Uplisting Agreement will be two (2) years, subject to either party's right to terminate it in the event that the other party to the agreement breaches it in any material way.

## ITEM 8. EXHIBITS

### Index to Exhibits

<b>Exhibit No.</b>	<b>Exhibit Description</b>
2.1	Certificate of Incorporation (Incorporated by reference to Exhibit 2.1 of Form DOS filed with the Securities and Exchange Commission on August 19, 2016).
2.2	Bylaws (Incorporated by reference to Exhibit 2.2 of Form DOS filed with the Securities and Exchange Commission on August 19, 2016).
4.1	Form of Subscription Agreement (Incorporated by reference to Exhibit 4.1 of Form DOS/A filed with the Securities and Exchange Commission on September 29, 2016).
6.1	Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., dated May 1, 2016 (Incorporated by reference to Exhibit 6.1 of Form DOS/A filed with the Securities and Exchange Commission on September 29, 2016).
6.2	Management Services Agreement, as amended, with Avalanche International Corp., dated May 1, 2016 (Incorporated by reference to Exhibit 6.2 of Form DOS/A filed with the Securities and Exchange Commission on September 29, 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 (Incorporated by reference to Exhibit 6.3 of Form 1-K filed with the Securities and Exchange Commission on February 21, 2019).
6.4	Standard Exclusive License Agreement with Sublicensing Terms Number LIC18111 with the University of South Florida Research Foundation, Inc., dated July 2, 2018 (Incorporated by reference to Exhibit 6.4 of Form 1-K filed with the Securities and Exchange Commission on February 21, 2019).
6.5	Employment Agreement with Henry Nisser effective May 1, 2019. Filed herewith.

**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: August 28, 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: August 28, 2019

By: /s/ Kenneth S. Cragun  
Kenneth S. Cragun  
Chief Financial Officer  
(Principal Financial Officer,  
Principal Accounting Officer).

## EXECUTIVE EMPLOYMENT AGREEMENT

This EXECUTIVE EMPLOYMENT AGREEMENT (this “**Agreement**”) is made and entered into as of this May 20, 2019 and effective as of May 1, 2019 (**Effective Date**), by and between Alzamend Neuro, Inc., a Delaware corporation with an address of 100 Park Avenue, Suite 1658A, New York, NY 10017 (the “**Company**”) and Henry Nisser, an individual (the “**Executive**”).

## W I T N E S S E T H

**WHEREAS**, the Executive desires to be employed by the Company as its General Counsel and Executive Vice President and the Company wishes to employ Executive in such capacity;

**NOW, THEREFORE**, in consideration of the foregoing recitals and the respective covenants and agreements of the parties contained in this Agreement, the Company and Executive hereby agree as follows:

**1. Employment and Duties.** The Company agrees to employ and Executive agrees to serve as the Company's General Counsel, Executive Vice President and Secretary. The rights, duties and responsibilities of Executive shall include managing transactional operations of the Company and advising the Executive Chairman (the “**Chairman**”) and Board of Directors of the Company (the “**Board**”), as well as such other duties and responsibilities as are consistent with Executive's position. Executive shall report to the Chairman and the Board.

Executive shall devote a sufficient amount of his working time and efforts during the Company's normal business hours to the business and affairs of the Company and its subsidiaries in order to diligently and faithfully perform his duties and responsibilities duly assigned to him pursuant to this Agreement. Executive shall be permitted to carry on additional activities provided that none of the additional activities interferes with the performance of the duties and responsibilities of Executive or are determined to be inconsistent with the position, standing, stature, reputation or best interests of the Company; nothing in this Section 1, shall prohibit Executive from (a) serving as a director or member of a committee of entities that do not, in the reasonable good faith determination of the Board, compete with the Company or otherwise create, or could create, in the reasonable good faith determination of the Board, a conflict of interest with the business of the Company; (b) delivering lectures, fulfilling speaking engagements, and any writing or publication relating to his area of expertise; (c) serving as a director or trustee of any governmental, charitable or educational organization; or (d) engaging in additional activities in connection with personal and/or business investments and community affairs.

Executive shall supervise all legal personnel, whether hired or engaged on a transactional basis, of the Company and each of its Subsidiaries.

**2. Term.** The term of this Agreement shall commence on the Effective Date and shall continue through May 1, 2023 (the “**Term**”) unless earlier terminated by either party providing the other party with written notice of his or its intention to terminate this Agreement upon thirty (30) days' notice.

**3. Place of Employment.** Executive's services may, but need not, be performed at the Company's offices at the address in the first paragraph above. The Executive may from time to time perform his duties to the Company at another location or locations, at the discretion of Executive. The parties acknowledge, however, that Executive may be required to travel in connection with the performance of his duties hereunder.

**4. Base Salary.** For all services to be rendered by Executive pursuant to this Agreement, the Company agrees to pay Executive during the Term a base salary at an annual rate of \$50,000 (the “**Base Salary**”). In addition, the Base Salary as then in effect shall be subject to such further upward adjustments as shall be determined by the Board in its sole discretion. The Base Salary shall be paid in periodic installments in accordance with the Company's regular payroll practices.

**5. Bonuses.** During the Term, the Executive shall be entitled to an annual bonus (the “**Annual Bonus**”) if the Company meets or exceeds criteria adopted by the Board for earning Bonuses which shall be adopted by the Board annually. Bonuses shall be paid by the Company to the Executive promptly after determination that the relevant targets have been met, it being understood that the attainment of any financial targets associated with any bonus shall not be determined until following the completion of the Company's annual audit and public announcement of such results and shall be paid promptly following the Company's announcement of earnings.

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The Board may provide for lesser or greater percentage Bonus payments for Executive upon achievement of partial or additional criteria established or determined by the Board from time to time. For the avoidance of doubt, if Executive is employed immediately prior to the expiration of the term of this Agreement, he shall be entitled to the Annual Bonus for such last year on a pro-rata basis through the last date of employment, even if he is not employed by the Company on the date the Annual Bonus is paid for such last year. The Company and Executive shall negotiate in good faith the 2019 budget as soon as reasonably practicable after the date hereof.

In addition to the foregoing, additional bonuses may be awarded by the Board. Any such bonus shall be paid by the Company to the Executive promptly after determination that if any targets relate to fiscal period performance having been met, it being understood that the attainment of any financial targets associated with any bonus shall not be determined until following the completion of the Company's annual audit and public announcement of such results and shall be paid to Executive promptly following the Company's announcement of earnings.

**6. Reserved.**

**7. Equity Awards.** As of the date hereof the Company shall grant to Executive an option to purchase 1,250,000 shares of the Company's common stock exercisable for a period of five (5) years at a per share exercise price of \$1.50. The options shall vest ratably over 48 months beginning with the first month after the Effective Date.

The Company agrees, upon becoming subject to the Section 12 of the Securities Exchange Act of 1934, as amended, to register all shares of Common Stock issued to the Executive on Form S-1 or a successor form thereto as promptly as reasonably practicable.

**8. Expenses.** Executive shall be entitled to prompt reimbursement by the Company for all reasonable and necessary travel, entertainment, and other expenses incurred by Executive while employed (in accordance with the policies and procedures established by the Company for its senior executive officers) in the performance of his duties and responsibilities under this Agreement; provided, that Executive shall properly account for such expenses in accordance with Company policies and procedures. Notwithstanding anything herein or in the Company's policies and procedures to the contrary, Executive shall be reimbursed for all travel expenses and shall be entitled to travel and lodging equal to business class or greater.

**9. Other Benefits.**

(a) Benefit Plans. During the term of this Agreement, the Executive shall be eligible to participate in incentive, stock purchase, savings, retirement (401(k)), and welfare benefit plans, including, without limitation, health, medical, dental, vision, life (including accidental death and dismemberment) and disability insurance plans (collectively, "**Benefit Plans**"), in the same manner and at the same levels as the Company makes such opportunities available to the Company's managerial or salaried executive employees. In the event that any waiting periods or other eligibility requirements are imposed prior to Executive becoming eligible for any of such Benefit Plans, then the Company shall reimburse Executive for the cost(s) incurred by Executive in maintaining his current benefit plans during any such waiting or eligibility periods.

(b) Insurance. The Company shall obtain directors & officers and malpractice insurance for the Executive in a reasonable amount, and maintain such coverage with respect to any events that may occur during Executive's employment hereunder.

(c) Vacation. The Executive shall be entitled to 4 weeks of vacation (in addition to the usual national holidays) during each contract year during which he serves hereunder. Such vacation shall be taken at such time or times as will be mutually agreed between the Executive and the Company. Vacation not taken during a calendar year may be carried forward, with a maximum accrual of 16 weeks.

**10. Reserved.**

**11. Confidential Information.**

(a) **Disclosure of Confidential Information.** The Executive recognizes, acknowledges and agrees that he has had and will continue to have access to secret and confidential information regarding the Company, its subsidiaries and their respective businesses ("**Confidential Information**"), including but not limited to, its products, methods, formulas, software code, patents, sources of supply, customer dealings, data, know-how, trade secrets and business plans, provided Confidential Information shall not include information and know how that was known to Executive prior to his employment hereunder, is in or does hereafter become part of the public domain, or becomes known to others through no fault of the Executive. The Executive acknowledges that such Confidential Information is of great value to the Company, is the sole property of the Company, and has been and will be acquired by him in confidence. In consideration of the obligations undertaken by the Company herein, the Executive will not, at any time, during or after his employment hereunder, reveal, divulge or make known to any person, any Confidential information acquired by the Executive during the course of his employment, which is treated as confidential by the Company, and not otherwise in the public domain. The provisions of this Section 11 shall survive the termination of the Executive's employment hereunder.

(b) The Company acknowledges that notwithstanding the foregoing, Executive, through his extensive experience and contacts in the industry is already in possession of significant information and know how regarding the Company, its products and the industry within which it operates. Nothing herein shall be deemed to restrict Executive, during the term hereof or thereafter, from disclosing or using any such information.

(c) In the event that the Executive's employment with the Company terminates for any reason, the Executive shall deliver forthwith to the Company any and all originals and copies, including those in electronic or digital formats, of Confidential Information; provided, however, that Executive shall be entitled to retain (i) papers and other materials of a personal nature, including, but not limited to, photographs, correspondence, personal diaries, calendars and rolodexes, personal files and phone books, (ii) information showing his compensation or relating to reimbursement of expenses, (iii) information that he reasonably believes may be needed for tax purposes and (iv) copies of plans, programs and agreements relating to his employment, or termination thereof, with the Company.

**12. Non-Competition and Non-Solicitation.** To the fullest extent permissible under applicable law, during the term of this Agreement and for a period of two (2) years following termination of this Agreement (the "**Separation Period**");

(a) The Executive agrees and acknowledges that the Confidential Information that the Executive has already received and will receive is valuable to the Company and that its protection and maintenance constitutes a legitimate business interest of the Company, to be protected by the non-competition restrictions set forth herein. The Executive agrees and acknowledges that the non-competition restrictions set forth herein are reasonable and necessary and do not impose undue hardship or burdens on the Executive. The Executive also acknowledges that the products and services developed or provided by the Company, its affiliates and/or its clients or customers are or are intended to be sold, provided, licensed and/or distributed to customers and clients primarily in and throughout the United States (the "**Territory**") (to the extent the Company comes to operate, either directly or through the engagement of a distributor or joint or co-venturer, or sell a significant amount of its products and services to customers located, in areas other than the United States during the term of the Term, the definition of Territory shall be automatically expanded to cover such other areas), and that the Territory, scope of prohibited competition, and time duration set forth in the non-competition restrictions set forth below are reasonable and necessary to maintain the value of the Confidential Information of, and to protect the goodwill and other legitimate business interests of, the Company, its affiliates and/or its clients or customers. The provisions of this Section 12 shall survive the termination of the Executive's employment hereunder.



(b) The Executive hereby agrees and covenants that he shall not, during the Term and any Separation Period, without the prior written consent of the Company, directly or indirectly, in any capacity whatsoever, including, without limitation, as an employee, employer, consultant, principal, partner, shareholder, officer, director or any other individual or representative capacity (other than (i) as a holder of less than five percent (5%) of the outstanding securities of a Company whose shares are traded on any national securities exchange or (ii) as a limited partner, passive minority interest holder in a venture capital fund, private equity fund or similar investment entity which holds or may hold an equity or equity-linked security position in portfolio companies that are directly competitive with the Company's products or services; provided however, that the Executive shall be precluded from serving as an operating partner, general partner, manager or governing board designee with respect to such portfolio companies), or whether on the Executive's own behalf or on behalf of any other person or entity or otherwise howsoever, during the Term and the Separation Period and thereafter to the extent described below, within the Territory:

(1) Engage, own, manage, operate, control, be employed by, consult for, participate in, or be connected in any manner with the ownership, management, operation or control of any business in direct competition with the business of the Company;

(2) Recruit, solicit or hire, or attempt to recruit, solicit or hire, any employee, or independent contractor of the Company to leave the employment (or independent contractor relationship) thereof, whether or not any such employee or independent contractor is party to an employment agreement, for the purpose of directly competing with the business of the Company;

(3) Attempt in any manner to solicit or accept from any customer of the Company, with whom Executive had significant contact during Executive's employment by the Company (whether under this Agreement or otherwise), business of the kind or competitive with the business done by the Company with such customer or to persuade or attempt to persuade any such customer to cease to do business or to reduce the amount of business which such customer has customarily done or might do with the Company, or if any such customer elects to move its business to a person other than the Company, provide any services of the kind or competitive with the business of the Company for such customer, or have any discussions regarding any such service with such customer, on behalf of such other person; or

(4) Interfere with any relationship, contractual or otherwise, between the Company and any other party, including, without limitation, any supplier, distributor, co-venturer or joint venturer of the Company, for the purpose of soliciting such other party to discontinue or reduce its business with the Company.

For purposes hereof, a business shall not be deemed to be in competition with the business of the Company, nor shall any products or services be deemed to compete with those of the Company, unless the Company presently produces, sells or distributes or, has, during the Term, plans to produce, sell or distribute, such products or services.

With respect to the activities described in Paragraphs (1), (2), (3) and (4) above, the restrictions of this Section 12(b) shall continue during the Term and until termination of the Separation Period following the termination of this Agreement or of the Executive's employment with the Company (including upon expiration of this Agreement), whichever occurs later; provided, however that, in the event this Agreement or Executive's employment is terminated by Executive for Good Reason or is terminated by Company without Cause, then the restrictions contained in Section 12(b) shall continue during the Term, and not beyond.

### **13. Miscellaneous.**

(a) The Executive acknowledges that the services to be rendered by him under the provisions of this Agreement are of a special, unique and extraordinary character and that it would be difficult or impossible to replace such services. Furthermore, the parties acknowledge that monetary damages alone would not be an adequate remedy for any breach by the Executive of Section 11 or Section 12 of this Agreement. Accordingly, the Executive agrees that any breach or threatened breach by him of Section 11 or Section 12 of this Agreement shall entitle the Company, in addition to all other legal remedies available to it, to apply to any court of competent jurisdiction to seek to enjoin such breach or threatened breach. The parties understand and intend that each restriction agreed to by the Executive hereinabove shall be construed as separable and divisible from every other restriction, that the unenforceability of any restriction shall not limit the enforceability, in whole or in part, of any other restriction, and that one or more or all of such restrictions may be enforced in whole or in part as the circumstances warrant. In the event that any restriction in this Agreement is more restrictive than permitted by law in the jurisdiction in which the Company seeks enforcement thereof, such restriction shall be limited to the extent permitted by law. The remedy of injunctive relief herein set forth shall be in addition to, and not in lieu of, any other rights or remedies that the Company may have at law or in equity.

(b) Neither the Executive nor the Company may assign or delegate any of their rights or duties under this Agreement without the express written consent of the other; *provided, however*, that the Company shall have the right to delegate its obligation of payment of all sums due to the Executive hereunder, provided that such delegation shall not relieve the Company of any of its obligations hereunder.

(c) During the term of this Agreement, the Company (i) shall indemnify and hold harmless Executive and his heirs and representatives as provided under the Company's certificate of incorporation, bylaws and indemnification agreement and (ii) shall cover Executive under the Company's directors' and officers' liability insurance on the same basis as it covers other senior executive officers and directors of the Company.

(d) This Agreement constitutes and embodies the full and complete understanding and agreement of the parties with respect to the Executive's employment by the Company, supersedes all prior understandings and agreements, whether oral or written, between the Executive and the Company, and shall not be amended, modified or changed except by an instrument in writing executed by the party to be charged (it being understood that, pursuant to Section 7, the Plan and relevant option agreements shall govern with respect to the subject matter thereof). The invalidity or partial invalidity of one or more provisions of this Agreement shall not invalidate any other provision of this Agreement. No waiver by either party of any provision or condition to be performed shall be deemed a waiver of similar or dissimilar provisions or conditions at the same time or any prior or subsequent time.

(e) This Agreement shall inure to the benefit of, be binding upon and enforceable against, the parties hereto and their respective successors, heirs, beneficiaries and permitted assigns. The headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement.

(f) All notices, requests, demands and other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given when personally delivered, sent by registered or certified mail, return receipt requested, postage prepaid, or by reputable national overnight delivery service (e.g. Federal Express) for overnight delivery to the party at the address set forth in the preamble to this Agreement, or to such other address as either party may hereafter give the other party notice of in accordance with the provisions hereof. Notices shall be deemed given on the sooner of the date actually received or the third business day after deposited in the mail or one business day after deposited with an overnight delivery service for overnight delivery.

(g) Choice of Law, Jurisdiction and Venue. The corporate laws of the State of New York shall govern all issues concerning this Agreement. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting the New York, New York, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction. EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.

(h) This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one of the same instrument. The parties hereto have executed this Agreement as of the date set forth above.

(i) The Executive represents and warrants to the Company, that he has the full power and authority to enter into this Agreement and to perform his obligations hereunder and that the execution and delivery of this Agreement and the performance of his obligations hereunder will not conflict with any agreement to which Executive is a party. The Company represents and warrants to Executive that it has the full power and authority to enter into this Agreement and to perform its obligations hereunder and that the execution and delivery of this Agreement and the performance of its obligations hereunder will not conflict with any agreement to which the Company is a party.

**[Signature page follows immediately]**

IN WITNESS WHEREOF, the Executive and the Company have caused this Executive Employment Agreement to be executed as of the date first above written.

**ALZAMEND NEURO, INC.**



By: \_\_\_\_\_  
Name: Milton C. Ault, III  
Title: Executive Chairman

**EXECUTIVE**



By: \_\_\_\_\_  
Name: Henry Nisser