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, 2020**

ALZAMEND NEURO, INC.

(Exact name of issuer as specified in its charter)

Delaware	**2834**	**81-1822909**
State or other jurisdiction of incorporation or organization	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

3802 Spectrum Boulevard, Suite 112C
Tampa, Florida 33612
(Full mailing address of principal executive offices)

(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.
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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.

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 Annual Report 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.

Alzamend 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 as a vaccine or prophylactic against Alzheimer's. This treatment, known as AL002 (formerly known as CAO22W), has transitioned from early stage development to an extensive program of preclinical study and evaluation with an anticipated completion date in the fourth quarter of calendar year 2020. AL002 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 ("**IND**") application with the United States Food and Drug Administration (the "**FDA**") with respect to AL002 in the fourth quarter of calendar year 2020 and prepare to conduct a Phase 1 Clinical Trial in the fourth quarter of calendar year 2020.

On July 2, 2018, we obtained two royalty-bearing, exclusive worldwide licenses from the Licensor to a therapy known as AL001 (formerly known as LiProSal) to mitigate extreme agitation and forestall other deterioration as displayed by patients with mild to moderate AD. AL001 is an ionic cocrystal of lithium and has been shown to exhibit improved nonclinical pharmacokinetics compared to current FDA-approved lithium products; it is also bioactive in many in vitro models of Alzheimer's. AL001 is expected to provide clinicians with a major improvement over current lithium-based treatments and may also constitute a means of treating Alzheimer's and other neurodegenerative diseases. Based on nonclinical data, AL001 co-crystal technology has the potential to improve the therapeutic index of lithium providing a greater bioavailability to the site of action (brain) 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, mitigating the potential regulatory burden for safety data. We submitted a pre-IND briefing package to the FDA in July 2019 that argued against the need for any further preclinical safety studies. Per the FDA response letter, we believe the proposed test parameters for AL001 appears reasonable to support a Phase 1 study, thereby allowing us to conduct human clinical trials. Post Phase III clinical trials and in order to obtain approval to commercialize AL001 via a New Drug Application ("**NDA**"), Alzamend has been asked to provide a scientific bridge to a listed drug to support the adequacy of the nonclinical program. Per the FDA, the adequacy of the nonclinical data will be a matter of review. If the adequacy of the nonclinical data is not sufficient for the FDA, Alzamend will then be required to conduct a clinical pharmacokinetics animal study (6-weeks study) of AL001 in order to be considered for FDA approval. We received feedback from the FDA regarding the pre-IND briefing package and have begun the process of finalizing the IND application and, while FDA approval is not guaranteed, we expect to receive approval to begin a Phase 1 Clinical Trial with human subjects in the fourth quarter calendar year 2020. While the FDA has not given us any indication as to whether AL001 will receive Breakthrough Therapy designation or be permitted to use the 505(b)(2) regulatory pathway, we believe that AL001 is an ideal candidate to receive both a Breakthrough Therapy designation as well as a section 505(b)(2) regulatory pathway for new drug approvals, enhancing the speed and reducing the regulatory burden of FDA review.

Technology

AL001

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 pharmaceutics (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 as a mood stabilizer in treating patients with bipolar disorder, it is still used clinically despite its narrow therapeutic index. This has led researchers to begin to look for alternatives to lithium with similar bioactivities.

The inventors from the University of South Florida (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 physiochemical 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, results from 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 team of inventors from the University have specifically designed, synthesized and characterized the novel ionic cocrystal of lithium (known as AL001). AL001 has been shown to exhibit improved nonclinical pharmacokinetics compared to current FDA-approved lithium products; it is also bioactive in many in vitro models of Alzheimer's. AL001 is expected to provide clinicians with a major improvement over current lithium-based treatments and may also constitute a means of treating Alzheimer's and other neurodegenerative diseases and psychiatric disorders.

A product can be designated as a Breakthrough Therapy 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 a 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 believe that AL001 is ideally positioned for a Section 505(b)(2) regulatory pathway for new drug approvals. The Section 505(b)(2) regulatory pathway provides manufacturers with an opportunity to obtain FDA approval without performing all the work that's required by 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 AL001 would be eligible for 3-5 years of market exclusivity during which period AL001 would be protected from competitors. If we successfully acquire a Breakthrough Therapy designation and the Section 505(b)(2) regulatory pathway for new drug approvals, we believe we can receive FDA approval for AL001 in four years.

AL001 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 AL001, our long-term business plans will not be met, and we will be unable to generate the revenue we have forecast for many years, if any. We do not anticipate that we will generate our maximum revenue for several years, or that we will achieve profitability for this therapeutic until at least a few years after generating material revenue, if at all. If we are unable to generate revenue, we would not be able to pursue any expansion of our business or acquire additional intellectual property as we have planned, we will not become profitable with this therapeutic agent, and we would be unable to continue our operations as currently planned.

AL002

The other patented solution that we have licensed to move to commercialization is AL002, a mutant-peptide immunotherapy designed to be used as a vaccine or prophylactic against Alzheimer's. 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 that ultimately lead 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 an immune response 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 towards 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.

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 individuals with 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.

AL002 has been researched for more than ten years and we are currently in the midst of completing its preclinical development and have begun both the pre-IND and IND application process with 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 study for AL002 with Charles River Laboratories, Inc. ("**CRL**") in compliance with FDA requirements. Upon conclusion of this toxicological study, anticipated to occur at the end of November 2020, 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. AL002 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 AL002, our long-term business plans will not be met, and we will be unable to generate the revenue we have forecast for AL002 for many years, if any. We do not anticipate that we will generate our maximum revenue for several years, or that we will achieve profitability for this therapeutic until at least a few years after generating material revenue, if at all. If we are unable to generate revenue, we would not be able to pursue any expansion of our business or acquire additional intellectual property as we have planned, we will not become profitable with this therapeutic agent, and we would be unable to continue our operations as currently planned.

Market

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. The Alzheimer's Association estimates that the cost of caring for people with Alzheimer's and other dementias will reach $305 billion in 2020 and that by 2050, these costs may rise as high as $1.1 trillion. Since 1990, life expectancy has increased by six 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, one 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 vaccine, therapeutic or cure is not found. Many Alzheimer's related associations believe the actual number of adults with AD may be as much as five times more, or 30 million, since current statistics do not take into 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 one in three 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 approved by the FDA and available to the public. 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. We have begun the process of finalizing the IND application for AL001 and expect to receive approval to begin a Phase 1 Clinical Trial with human subjects in the fourth quarter calendar year 2020.

We expect to begin the process of finalizing the IND application process for AL002 and move quickly forward to begin a Phase 1 Clinical Trial with human subjects during the second quarter of calendar year 2021.

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 clinical activities. We have also retained a division of the international Swiss manufacturer, Lonza, to develop the manufacturing protocols, processes and procedures. 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 (Director of the NYU Pearl Barlow Center for Memory Evaluation and Treatment) and Dr. Eric McDade (Associate Director of the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU)). The SAB members have clinical specializations, including extensive experience with AD and other neurological diseases. We intend to rely on these 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 and highly-regarded regulatory consultancy firm based in Georgia for project management. In this capacity, TAMM Net will 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 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. Chuanhai Cao, the neuroscientist who developed AL002, and his medical team for at least the next three years.

We obtained two royalty-bearing, exclusive worldwide licenses from the Licensor for AL001, a cocrystal biologic therapy intended to mitigate extreme agitation and forestall further deterioration of memory as displayed by patients with mild 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

AL001

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 pharmaceutics (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 physiochemical 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, results from 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 team of inventors from the University have specifically designed, synthesized and characterized the novel ionic cocrystal of lithium (known as AL001). AL001 has been shown to exhibit improved nonclinical pharmacokinetics compared to current FDA-approved lithium products, it is also bioactive in many in vitro models of Alzheimer's. AL001 is expected to provide clinicians with a major improvement over current lithium-based treatments and may also constitute a means of treating Alzheimer's and other neurodegenerative diseases.

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. While the FDA has not given us any indication as to whether AL001 will receive Breakthrough Therapy designation or be permitted to use the 505(b)(2) regulatory pathway, we believe that AL001 is an ideal candidate to receive both a Breakthrough Therapy designation as well as a section 505(b)(2) regulatory pathway for new drug approvals, enhancing the speed and reducing the regulatory burden of FDA review. The Section 505(b)(2) regulatory pathway provides manufacturers with an opportunity to acquire FDA approval without performing all the work 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 AL001 is eligible for 3-5 years of market exclusivity during which period AL001 would be protected from competitors. If we successfully acquire a Breakthrough Therapy designation and the Section 505(b)(2) regulatory pathway for new drug approvals, we believe we can receive FDA approval for AL001 in four years.

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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 individuals with 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.

AL002 has been researched for more than 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 study for AL002 with CRL in compliance with FDA requirements. Upon conclusion of this toxicological study, anticipated to occur in the fourth quarter of calendar year 2020, 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. AL002 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 AL002, our long-term business plans will not be met, and we will be unable to generate the revenue we have forecast for AL002 for many years, if any. 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 any. If we are unable to generate revenue, we will not be able to pursue any expansion of our business or acquire additional intellectual property as we have planned, we will not become profitable with this therapeutic agent, and we would be unable to continue our operations as currently planned.

Our Science

Therapeutic Drug	Synopsis	Strength	Status
AL001	• Use of patented Ionic Cocrystal (ICC) technology delivering a therapeutic combination of Lithium, Proline, and Salicylate • Lithium as a treatment of agitation and other possible symptoms in patients with indication of Alzheimer's disease • Other potential indications: Dementia, Parkinson's Disease, ALS, Depression, Bi-Polar Disorder, Mania, Post Traumatic Stress Disorder (PTSD), Suicidality, etc.	• Exclusive license for Cocrystal delivery system for AD and psychiatric indications • Eligible for "breakthrough therapy" designation from FDA • Seeking a 505(b)(2) clinical trial pathway from FDA • Formulation may importantly expand the range of therapeutic categories amenable to lithium treatments, with enhanced safety • Has the potential of becoming the replacement for all lithium therapy on the market	• Filed Pre-IND in Q3, 2019 • Planned filing of IND in Q4, 2020 • Planned commencement of Phase 1 human clinical trials in Q4, 2020
AL002	• 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. • Also seeks to mitigate adverse reactions from a patient's immunological system experienced during pre-clinical trials including the highly publicized Elan study (AN-1972)	• Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of AD • Difficult to manufacture and hence not easily replicated by competitors • Eligible for "breakthrough therapy" status via FDA • Antibody responses induced after one inoculation (Pre-Clinical) and lasted for four months • Inflammation cytokines like IL1 and TNF.alpha, which are considered to be related to inflammation didn't increase with antibody level increase	• Completing pre-clinical studies Q4, 2020 • Planned filing IND in Q1, 2021 • Planned commencement of Phase 1 human clinical trials in Q1, 2021

Market Opportunity

The Alzheimer's Association estimates that the cost of caring for people with Alzheimer's will reach $305 billion dollars in 2020 and by 2050, these costs may rise as high as $1.1 trillion. Currently, Alzheimer's is the 6 th leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. Alzamend was formed to develop and commercialize patented intellectual property/treatments for Alzheimer's, by funding it from pre-clinical 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 cited 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 the Asia-Pacific region - 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. We believe there will be several sources of manufacturing available once a therapy or treatment can achieve Phase 2 study.

For AL001, we have selected Alcami, a contract development, manufacturing, and testing organization headquartered in North Carolina with over 40 years of experience advancing products through every stage of the development lifecycle. Approximately 900 Alcami employees across six sites in the United States serve biologics and pharmaceutical companies of all sizes, helping to deliver breakthrough therapies to patients faster. Alcami provides customizable and innovative solutions for API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (parenteral and oral solid dose), packaging, and stability services.

For AL002, 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 AL001 and AL002 through successive de-risking milestones towards regulatory approval and seek marketing approval of AL001 and AL002, 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, though 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**"), resulting in 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 they accept 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 AL001 or AL002.

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 AL001 or AL002 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 AL001 or AL002, 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 AL001 or AL002 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 foreign countries 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 AL001 and AL002 in the first half of 2021.

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 drugs designed to be used by humans 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 on the drug in 90 days. After the assessment is completed, copies of the report are sent to all Member States, together with the approved summary of product characteristics, labeling and package leaflet. The concerned Member States then have 90 days to recognize the decision of the reference Member State and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

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

Human Health Product Regulation in the Rest of World

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

Other Regulatory Considerations

Labeling, Marketing and Promotion

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

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

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

Anti-Kickback and False Claims Laws

In the U.S., we are subject to complex laws and regulations pertaining to health care "fraud and abuse," including, but not limited to, the Medicare and Medicaid Patient Protection Act of 1987 (also 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 $305 billion in 2020 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 2020 caregivers to people with Alzheimer's will provide 18.6 billion hours of care valued at $244 billion.

The cause and progression of Alzheimer's are not well understood. As of 2020, more than 2,386 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. Allied Market Research published a report, titled, Neurological Biomarkers Market for Alzheimer's and Parkinson's Diseases - Global Opportunity Analysis and Industry Forecast, 2018-2025. The report presents detailed analyses of the key market trends, drivers & opportunities, market size & forecasts, top investment pockets, and competitive landscape. According to the report, the neurological biomarkers market for Alzheimer's and Parkinson's disease was valued at $3.95 billion in 2017, and is expected to reach $8.57 billion by 2025, registering a CAGR of 10.1% from 2018 to 2025.

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 disease 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.

A summary of the licensed patents is as follows:

Patent Number	Therapy	Patent Title	Patent Type	Date Filed	Date Issued	Expiration Date	Jurisdiction
9,840,521 (USA) WO2012129568A2 (Europe)	AL001	Organic Anion Lithium Ionic Cocrystal Compounds and Compositions	Composition of Matter	04/19/2013	12/12/2017	04/19/2033	USA and Europe
9,603,869 (USA)	AL001	Lithium Cocrystals and an Additional Neuropsychiatric Agent for Treatment of Neuropsychiatric Disorders	Method of Use	05/21/2016	03/28/2017	05/21/2036	USA
8,188,046 (USA)	AL002	Amyloid beta peptides and methods of use	Method of Use	10/12/2007	05/29/2012	02/12/2028	USA

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.

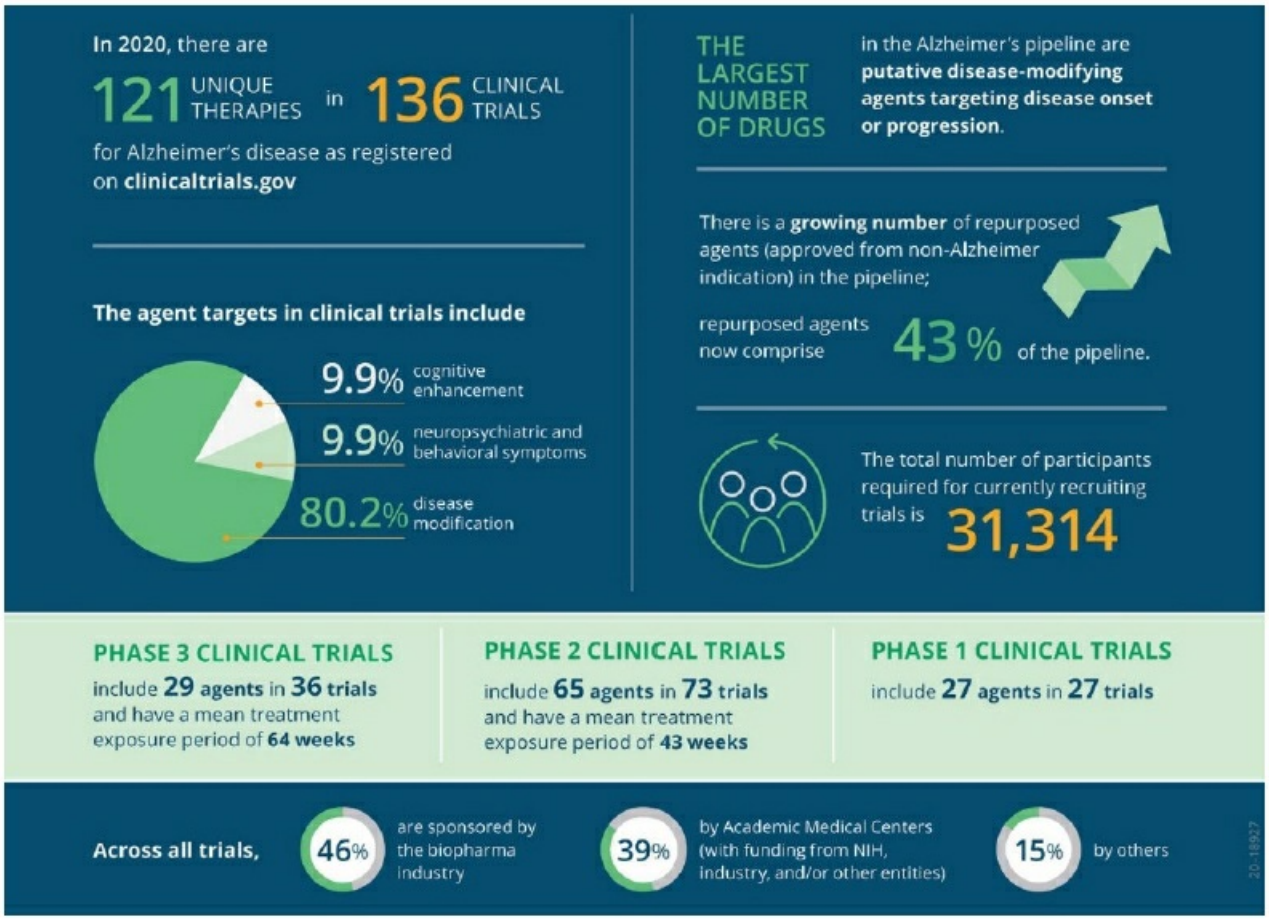
We currently possess four service trademarks with the U.S. PTO that include our corporate name, Alzamend Neuro; two for our corporate slogan and one for our trade name.

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



Current Drugs for Alzheimer's Disease

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

- Aricept – Eisai Co., Ltd. Third Quarter Financial Results (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.comews-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).
- Thomson Reuters Report - (https://www.researchgate.net/publication/274930518_Spotlight_on_Alzheimers_disease_a_Thomson_Reuters_Pharma_Matters_report).

Diagnostics for Alzheimer's Disease

Cerebrospinal Fluid (CSF)

CSF samples and protein assays of particular analytes remain the best tools in the diagnosis of Alzheimer's and encephalitis. The procedure involves a lumbar puncture - the insertion of a hallow 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 tracer 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 three 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 commercialization to lead our activities. On December 15, 2018, we accepted the resignation of our former CFO, William B. Horne and appointed our current CFO, Kenneth S. Cragun. On May 1, 2019 we hired Henry Nisser to be our General Counsel and Executive Vice President.

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 and the 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, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. In that case, the trading price of our shares of common stock could decline and you may lose all or part of your investment. See "Cautionary Note Regarding Forward Looking Statements" above for a discussion of forward-looking statements and the significance of such statements in the context of this Annual Report.

Risks Related to Our Company

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

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 53.7% 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 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, affiliates of our company beneficially own 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 could 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, 2020, we had cash of $90,285 and an accumulated deficit of $11,785,869. Since our inception, we have incurred recurring losses and for the year ended April 30, 2020, we incurred a net loss of $4,410,236. The report of our independent registered public accounting firm on our April 30, 2020, 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 offered to us on acceptable terms. If adequate working capital is not available we may be forced to cease or curtail our operations, which would cause investors to lose their entire investment.

We are at an early stage of development 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 AL001 and AL002 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 AL001 and AL002; and
- market acceptance of AL001 and AL002.

We only have two product candidates, AL001 and AL002, which are in the 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 AL001 or AL002, 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. Expansion of our operations, to include the development of AL001 and AL002, 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 AL001 or AL002 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.

We received a subpoena from the Commission in the investigation now known as "In the Matter of DPW Holdings, Inc.," the consequences of which are unknown.

We received a subpoena from the Commission that stated that the staff of the Commission is conducting an investigation now known as*"In the Matter of DPW Holdings, Inc.,"* and that the subpoena was issued as part of an investigation as to whether DPW Holdings, Inc. and certain of its officers, directors, employees, partners, subsidiaries and/or affiliates, and/or other persons or entities, directly or indirectly, violated certain provisions of the Securities Act and the Exchange Act, in connection with the offer and sale of its securities. Although the order states that the Commission may have information relating to such alleged violations, the subpoena expressly provides that the inquiry is not to be construed as an indication by the Commission or its staff that any violations of the federal securities laws have occurred. We have produced documents in response to the subpoena. The Commission may in the future require us to produce additional documents or information, or seek testimony from other members of our management team. We have received a notice from the Commission stating that its staff is investigating whether the Commission should issue an order pursuant to Rule 258 of Regulation A of the Securities Act that would temporarily suspend our Regulation A exemption.

We are unaware of the scope or timing of the Commissioner's investigation. As a result, we do not know how the Commission's investigation is proceeding or when the investigation will be concluded. We also are unable to predict what action, if any, might be taken in the future by the Commission or its staff as a result of the matters that are the subject to its investigation or what impact, if any, the cost of continuing to respond to subpoenas might have on our financial position, results of operations, or cash flows. We have not established any provision for losses in respect of this matter. In addition, complying with any such future requests by the Commission for documents or testimony could distract the time and attention of our officers and directors or divert our resources away from ongoing business matters. This investigation could result in significant legal expenses, the diversion of management's attention from our business, damage to our business and reputation, and could subject us to a wide range of remedies, including an enforcement action by the Commission. Two members of our board of directors, Messrs. Ault and Horne, are directors of DPW. There can be no assurance that any final resolution of this and any similar matters will not have a material adverse effect on our financial condition or results of operations.

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 AL002 while the License Agreements for AL001 require 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 AL002 and an initial license fee of $200,000 for AL001. As an additional licensing fee for the license of AL002, the Licensor received 3,601,809 shares of Common Stock. As an additional licensing fee for the license of the AL001 technologies, the Licensor received 2,227,925 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 consideration for our equity securities. Minimum royalties for AL001 are $25,000 in 2023, $45,000 in 2024 and $70,000 in 2025 and every year thereafter, for the life of the agreement. Minimum royalties for AL002 are $20,000 in 2022, $40,000 in 2023 and $50,000 in 2024 and every year thereafter, for the life of the agreement. Additionally, we are required to pay milestone payments on the due dates to the Licensor for the license of the AL001 technologies and for the AL002 technology, as follows:

AL001:

Payment	Due Date	Event
$ 50,000	Completed September 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

AL002:

Payment	Due Date	Event
$ 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 clinical 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

We have met the Pre-IND meeting milestone encompassing AL001. 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 investors 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 or any future 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 that 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 AL001 and AL002 and, potentially, other product candidates, for regulatory approval. Currently, however, neither AL001 nor AL002 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, AL001 and AL002. 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 AL001 or AL002.

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

- our timely initiation and successful completion of preclinical studies and clinical trials for AL001 or AL002;
- our demonstration to the satisfaction of the FDA, the EMA and other applicable regulatory authorities the safety and efficacy of AL001 or AL002 as well as to obtain regulatory and marketing approval for AL001 or AL002 in the U.S., Europe and elsewhere;
- our continued compliance with all clinical and regulatory requirements applicable to AL001 and AL002;
- our maintenance of an acceptable safety profile of AL001 and AL002 following regulatory approval;
- competition with other treatments;
- our creation, maintenance and protection of our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for AL001 and AL002;
- the effectiveness of our and our eventual partners' marketing, sales and distribution strategy and operations;
- the 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;
- our ability to launch commercial sales of AL002 or AL002 following regulatory approval, whether alone or in collaboration with others; and
- the acceptance of AL001 or AL002 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 AL001 or AL002. Our failure in any of the above factors, or in successfully commercializing AL001 or AL002 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.

AL001 and AL002 may not achieve market acceptance, which would limit our ability to generate revenue from new products.

Even if we develop AL001 or AL002 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 AL001, AL002, 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 AL001 or AL002 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 AL001 and AL002, independently of each other. The manufacturing of AL001 and AL002 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 AL001 and AL002, the responsibility to obtain market authorization for AL001 and AL002 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 AL001 and AL002 and we expect to retain legal responsibility for any future product candidates as well.

If we are unable to manufacture, or contract to manufacture, AL001 and AL002 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 AL001 and AL002 on a timely or cost-competitive basis, or preclude us from doing so at all.

Before we can begin commercial manufacture of AL001, AL002, 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 or those we contract with, 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 AL001 and AL002, 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 AL001, AL002 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 AL001 and AL002, 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 AL001 or AL002 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 AL001 or AL002, or limit the scope of any approved label or market acceptance.

If AL001, AL002 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, that:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of AL001 or AL002;
- 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 AL002 or AL001 is unlikely to receive regulatory approval or is unlikely to be successfully commercialized. In addition, regulatory agencies, an Institutional Review Board (an "**IRB**"), 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 AL001, AL002 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 AL001 or AL002 and materially impair our ability to generate revenue from the commercialization of AL001 or AL002 either by us or by any commercial partners with which we may develop a relationship 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 AL001 or AL002 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.

AL001 and AL002, 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 AL001 or AL002 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 AL001 or our Biologics License Application ("**BLA**") for AL002, then:
    - we may not be able to generate sufficient revenue or obtain financing to continue our operations;
    - our ability to execute our current business plan will be materially impaired;
    - our reputation in the industry and in the investment community would likely be significantly damaged; and
    - 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 AL001 or AL002 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 AL001 or AL002 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 AL001 or AL002 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.

The occurrence of 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 AL001 or AL002.

The research, testing, manufacturing, labeling, approval, sale, marketing and testing of AL001 and AL002 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 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 AL001, AL002 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, AL001, AL002 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 AL001 or AL002. 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.

AL001 or AL002 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 AL001, AL002 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 AL001, AL002 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 AL001, AL002 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 AL001, AL002 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 AL001, AL002 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 AL001 and AL002 to treat Alzheimer's. If AL001 or AL002 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 would limit its use. If we decide to attempt to develop, promote and commercialize new treatment indications and protocols for AL001, AL002 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 AL001 or AL002 could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize AL001 and AL002 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's 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 AL001 or AL002 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 AL001 or AL002, which could create material and significant limits on our ability to successfully commercialize AL001 and AL002 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 AL001 or AL002, 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, AL001, AL002 and other drug candidates were to become 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 (generally 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.

Further, 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 AL001, AL002 or any future product candidates, conduct our in-licensing and development efforts or commercialize AL001, AL002 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 AL002, and Dr. Roland "Doug" Shytle, one of the investors of AL001 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 AL001 or AL002. 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 AL001 or AL002.

We and our partners face potential product liability exposure related to the testing of AL001 or AL002 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 AL001 or AL002. Now, and in the future, an individual may bring a liability claim against us alleging that AL001 or AL002 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 AL001 or AL002, 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, or 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 AL001 or AL002 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 AL001 or AL002.

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 parts 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 AL001, AL002 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 AL001, AL002 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 AL001, AL002 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 AL001 or AL002. 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 AL001, AL002 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 AL001, AL002 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 AL001, AL002 or any future product candidates is threatened, it could threaten our ability to commercialize AL001, AL002 or any future product candidates. Further, if we encounter delays in our development efforts, the period of time during which we could market AL001, AL002 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 AL001, AL002, 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 AL001 and AL002.

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 AL001, AL002 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, 2020 AND 2019

The following table summarizes the results of our operations for the years ended April 30, 2020 and 2019.

ALZAMEND NEURO, INC.
Condensed Statements of Operations

	For the Year Ended April 30,	
	2020	**2019**
OPERATING EXPENSES		
Research and development	$ 1,069,418	$ 3,700,083
General and administrative	3,354,743	1,308,800
Total operating expenses	4,424,161	5,008,883
Loss from operations	(4,424,161)	(5,008,883)
OTHER INCOME (EXPENSE), NET		
Interest income - related party	13,925	146,387
Total other income (expense), net	13,925	146,387
NET LOSS	$ (4,410,236)	$ (4,862,496)
Basic and diluted net loss per common share	$ (0.06)	$ (0.08)
Basic and diluted weighted average common shares outstanding	71,253,580	58,843,040

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, AL001 and AL002. 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, 2020 and 2019, 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, 2020 and 2019, were $3,354,743 and $1,308,800, respectively. As reflected in the table below, general and administrative expenses primarily consisted of the following expense categories: stock compensation expense, professional fees, salaries and benefits, management services, and advertising and promotion. The remaining general and administrative expenses of $120,348 and $110,399, respectively, primarily consisted of payments for advertising and promotion, consulting, transfer agent fees, travel, and other office expenses, none of which is significant individually.

	For the Year Ended April 30,	
	2020	**2019**
Stock compensation expense	$ 1,945,741	$ 396,170
Professional fees	861,348	545,771
Salary and benefits	427,306	96,460
Management services	-	160,000
Other general and administrative expenses	120,348	110,399
Total general and administrative expenses	$ 3,354,743	$ 1,308,800

Stock compensation expense

During the years ended April 30, 2020 and 2019, we incurred general and administrative stock compensation expense of $1,945,741 and $396,170, respectively, related to stock option grants to executives, employees and consultants as well as shares issued for services to Spartan. All option grants are granted at the per share fair value on the grant date. Vesting of options differs based on the terms of each option. We valued the options at their date of grant utilizing the Black Scholes option pricing model. We valued the shares issued for services at their intrinsic value on the date of issuance. Stock-based compensation is a non-cash expense because we settle these obligations by issuing shares of our Common Stock from authorized shares instead of settling such obligations with cash payments.

Professional fees

The second largest component of our general and administrative expenses is professional fees. During the years ended April 30, 2020 and 2019, we reported professional fees of $861,348 and $545,771, respectively, which are principally comprised of the following items:

Year Ended April 30, 2020

- 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 years ended April 30, 2020, we recorded an expense of $280,000 in connection with this consulting agreement.

- In June 2019, we entered into a two-year uplisting agreement with Spartan pursuant to which Spartan has agreed to provide consulting services with respect to a potential public offering. Compensation under this agreement consisted of a cash payment in the amount of $475,000 and the issuance of 500,000 shares of our common stock. We are amortizing the cost of these services over the twenty-four (24) month term of the uplisting agreement. During the year ended April 30, 2020, we recorded an expense of $104,167 in connection with the uplisting agreement.

- During the year ended April 30, 2020, we incurred $243,789 in legal fees.

- During the year ended April 30, 2020, we incurred $73,100 in audit fees.

Year Ended April 30, 2019

- During the year ended April 30, 2019, we recorded an expense of $280,000 as a result of the June 2017 Spartan consulting agreement discussed above.

- 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.

Salaries and Benefits

During the years ended April 30, 2020 and 2019, we incurred employee-related expenses of $427,306 and $96,460, respectively. As of April 30, 2020, we had one full-time and three part-time employees. We appointed Mr. Stephan Jackman as CEO as of November 30, 2018. On December 15, 2018, we retained our current CFO, Kenneth S. Cragun. On May 1, 2019 we hired Henry Nisser to be our General Counsel and Executive Vice President.

Management services

On April 30, 2020, we had one full-time and three part-time employees. We accepted the resignation of our previous President and CEO, Philip Mansour, effective on November 18, 2018, and appointed Mr. Stephan Jackman as CEO on 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. On 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 Messrs. Jackman and 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 year ended April 30, 2019, we recognized $160,000 in management fees in connection with this agreement. At April 30, 2019, $75,000 was included within related party payable on our balance sheet. The MSA expired as of December 31, 2018.

Research and development expenses

Research and development expenses for the years ending April 30, 2020 and 2019, were $1,069,418 and $3,700,083, respectively. As reflected in the table below, research and development expenses primarily consisted of licenses and fees, professional fees and stock compensation.

	For the Year Ended April 30,	
	2020	2019
Licenses and fees	$ 50,487	$ 2,489,600
Professional fees	709,432	1,142,887
Stock compensation expense	309,499	-
Other research and development expenses	-	67,596
Total research and development expenses	$ 1,069,418	$ 3,700,083

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 AL002 requires us to pay royalty payments of 4% on net sales of products developed from the licensed technology while the AL001 License Agreements require 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 AL002 and an initial license fee of $200,000 for AL001. As an additional licensing fee for the license of AL002, the Licensor received 3,601,809 shares of Common Stock. As an additional licensing fee for the license of the AL001 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 AL002 technology and for the AL001 technologies.

During the years ended April 30, 2019, we incurred $2,227,923 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, 2020 and 2019, we reported professional fees of $709,432 and $1,142,887, respectively, which are principally comprised of professional fees attributed to various types of scientific services, including FDA consulting services.

Other (expense) income, net

During the years ended April 30, 2020 and 2019, we reported interest income, related party of $13,925 and $146,387, respectively, relating to a promissory note from Avalanche.

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 years ended April 30, 2020 and 2019.

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, 2020, we had cash of $90,285 and an accumulated deficit of $11,785,869. We have incurred recurring losses and reported a net loss for the year ended April 30, 2020, which totaled $4,410,236. In the past, we have financed our operations principally through issuances of promissory notes and equity securities. During the year ended April 30, 2020, we continued to obtain additional equity 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, 2020, 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 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. The balance outstanding on the AVLP Note as of April 30, 2020, was $100,915. Subsequent to year end, during the month of August 2020, the principal and accrued interest on the AVLP Note was paid in full.

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.

Between June 25, 2019 and October 31, 2019, the Company entered into subscription agreements for the purchase of 1,756,726 units at $1.50 for each unit purchased pursuant to its 2019 private offering (the "**2019 Offering**"). Each unit consisted of one (1) share of Common Stock and one (1) warrant to purchase one half (0.5) share of Common Stock. In aggregate, the 1,756,726 units represents 1,756,726 shares of Common Stock and 878,363 warrants with an exercise price of $3.00 per share for an aggregate purchase price of $2,635,089, or $1.50 per share. The 2019 Offering was conducted pursuant to the terms of a Confidential Private Placement Memorandum dated June 12, 2019 (the "**2019 PPM**"). As of April 30, 2020, in conjunction with the 2019 PPM, the Company incurred $395,263 in placement fees resulting in net proceeds to the Company of $2,239,826.

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:

Payment	Due Date	Event
$ 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 clinical 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:

Payment	Due Date	Event
$ 50,000	Completed September 2019	Pre-IND meeting
$ 65,000	6 months from IND filing date	IND application filing
$ 190,000	12 months from IND filing date	Upon first dosing of patient in a clinical trial
$ 500,000	12 months from first patient dosing	Upon Completion of first clinical trial
$ 1,250,000	12 months from completion of the first Phase II clinical trial	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	8 years from the effective date of the agreement	Upon FDA approval

Off-Balance Sheet Arrangements

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

ITEM 3. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

Name	Age	Position
Stephan Jackman	45	Chief Executive Officer
Kenneth S. Cragun	59	Chief Financial Officer
Henry Nisser	52	General Counsel and Executive Vice President
Milton C. Ault, III	50	Executive Chairman & Director
Philip E. Mansour	52	Director
William B. Horne	52	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.

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 Financial Officer of DPW Holdings, Inc. (NYSE: 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.

Henry C. W. Nisser
Mr. Nisser began working for Alzamend on a part-time basis on May 1, 2019. Since May 1, 2019, Mr. Nisser as serves as the Executive Vice President and General Counsel of DPW Holdings, Inc. 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 and has served as our Chairman since inception and as our Executive Chairman since November 2, 2018. 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 Holdings, Inc. ("**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 two 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 until August 19, 2020 when he resigned as its Chief Financial Officer and was appointed as its President. 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.

* 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.

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, 2020 was as follows:

Name and Principal Position	Cash Compensation ($)	Other Compensation ($) (1)	Total Compensation ($)
Stephan Jackman, Chief Executive Officer	$ 200,000	$ -	$ 200,000
Kenneth S. Cragun, Chief Financial Officer	$ 86,667	$ -	$ 86,667
Henry Nisser, General Counsel and Executive Vice President	$ 50,000	$ 802,366	$ 852,366

(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.

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, we recognized $160,000 in management fees. At April 30, 2020 and April 30, 2019, $58,567 and $75,000, respectively, was included within related party payable on our balance sheet. The MSA was terminated as of December 31, 2018.

In December 2018, we entered into a consulting agreement with Mr. Horne to provide 12 months of CFO transition consulting services for $50,000. Mr. Horne was paid $37,500 and $12,500 for the years ended April 30, 2020 and 2019, respectively.

Employment agreement with Stephan Jackman

On November 30, 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, the 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 AL001, and to $225,000 upon the approval of the FDA IND application for AL002. 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. The Annual Bonus, if any, shall in part be determined based upon the successful attainment of the following milestones.:

- Approval to conduct a Second Phase Clinical Trial for AL002;
- Approval to conduct a Third Phase Clinical Trial for AL002;
- Approval to conduct a Third Phase Clinical Trial for AL001;
- Equity or debt financings

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 AL001 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 AL002 by the FDA within 48 months from November 1, 2018.

On November 1, 2019, Mr. Jackman's base salary was increased to $225,000.

On November 26, 2019, the Board of Directors granted 2,000,000 performance- and market-contingent awards to Mr. Jackman. These awards have an exercise price of $1.50 per share. These awards have multiple separate market triggers for vesting based upon either (i) the successful achievement of stepped target closing prices on a national securities exchange for 90 consecutive trading days later than 180 days after the Company's initial public offering for its common stock, or (ii) stepped target prices for a change in control transaction. The target prices range from $15 per share to $40 per share. In the event any the stock price milestones are not achieved within three years, the unvested portion of the performance options will be reduced by 25%.

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. The Annual Bonus, if any, shall in part be determined based upon the successful attainment of the following milestones:

- Approval to conduct a Second Phase Clinical Trial for AL002;
- Approval to conduct a Third Phase Clinical Trial for AL002;
- Approval to conduct a Third Phase Clinical Trial for AL001;
- Equity or debt financings

While the offer letter for Mr. Cragun stated an option life of seven (7) years, Mr. Cragun received a board-approved 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.

On November 1, 2019, Mr. Cragun's base salary was increased to $100,000.

On November 26, 2019, the Board of Directors granted 1,000,000 performance- and market-contingent awards to Mr. Cragun. These awards have an exercise price of $1.50 per share. These awards have multiple separate market triggers for vesting based upon either (i) the successful achievement of stepped target closing prices on a national securities exchange for 90 consecutive trading days later than 180 days after the Company's initial public offering for its common stock, or (ii) stepped target prices for a change in control transaction. The target prices range from $15 per share to $40 per share. In the event any the stock price milestones are not achieved within three years, the unvested portion of the performance options will be reduced by 25%.

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, 2020, held by (i) each person known to us to be the beneficial owner of more than ten percent (10%) 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, 2020, there were 64,762,858 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.

Directors and Officers	Number of shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned
Philip E. Mansour (1)	2,500,000	3.77%
Milton C. Ault, III (2)(3)(4)	55,000,000	50.57%
William B. Horne (1)	2,500,000	3.77%
Stephan Jackman (5)	1,312,500	2.02%
Kenneth S. Cragun (5)	625,000	0.97%
Henry Nisser (5)	416,667	0.65%
All directors and named executive officers as a group (6 persons)	62,354,167	53.70%
Greater than 10% Beneficial Owners:		
Ault Life Sciences, Inc. (3)	37,500,000	37.03%
Ault Life Sciences Fund, LLC (4)	15,000,000	21.81%

1) Consists of options to purchase 2,500,000 shares of Common Stock that are exercisable within 60 days of July 31, 2020.

(2) Includes options to purchase 2,500,000 shares of Common Stock that are exercisable within 60 days of July 31, 2020.

(3) Includes 750,000 Series A Preferred Shares held by Ault Life Sciences, Inc. that are convertible into 15,000,000 shares of Common Stock but carry the voting power of 37,500,000 shares of Common Stock. The control person of Ault Life Sciences, Inc. is Mr. Ault, the Executive Chairman of our company.

(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, 2020. 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, 2020. 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 for a purchase price of $8,000. The Series A Convertible Preferred Stock is convertible at a ratio 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 year ended April 30, 2019 we recognized $160,000 in management fees. At April 30, 2020 and April 30, 2019, $58,567 and $75,000, respectively, was included within related party payable on our balance sheet. The MSA expired on December 31, 2018.

In December 2018, we entered into a consulting agreement with Mr. Horne to provide 12 months of CFO transition consulting services for $50,000.

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 to MCKEA 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 5,000,000 shares of Common Stock were transferred by MCKEA to Spartan on January 31, 2018.

The amount due at April 30, 2019 to MCKEA and our officers for reimbursement of expenses paid and incurred by these related parties was $6,736 and was paid during the year ended April 30, 2020. The amount is included within related party payable on our balance sheet.

On April 10, 2018, the Company entered into a Note Receivable Agreement with Avalanche in the amount of $995,500, 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. The balance outstanding on the AVLP Note as of April 30, 2020, was $100,915. Subsequent to year end, during the month of August 2020, the principal and accrued interest on the AVLP Note was paid in full.

On April 30, 2019, we entered into a Security Purchase Agreement ("SPA") with Ault Life Science Fund ("ALSF") for the purchase of 10,000,000 shares of the Company's Common Stock plus 5,000,000 warrants with a 5-year life and an exercise price of $3.00 per share and vesting upon issuance (the "**ALSF Warrants**"). The total purchase price of $15,000,000 was in the form of a Note from Ault ALSF. The Note balance as of April 30, 2020 was reduced by $16,800 reflecting payments made during the year ended April 30, 2020. The control person of ALSF is Mr. Ault, the Executive Chairman of our company.

The Note is secured by a pledge of the purchased shares. While the SPA provides for ALSF's ability to pledge the securities acquired thereby, given that the purchased securities are subject to the SPA, we and ALSF agree that such securities may not be pledged to any third party until the current pledge agreement has been terminated through full repayment of the Note.

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, and the right to participate in any future financing the Company may consummate. All these rights, other than the right to participate in future financings which will not terminate until ALSF no longer holds any shares of Common Stock or any ALSF Warrants, will terminate on the earlier to occur of such date that we have (i) completed a Qualified Financing, or (ii) received approval by the FDA for any of our product candidates in Phase 3 clinical trial. For purposes of the SPA, a "**Qualified Financing**" means the sale of equity securities by us in a single transaction or a series of related transactions whether or not registered under the Securities Act, resulting in gross proceeds to us of no less than $25,000,000.

In addition, the SPA entitles ALSF the right to have all the shares of Common Stock to which it is entitled under the SPA be registered under the Securities Act within 180 days of the final closing of an initial public offering.

The Company agreed to enter into the SPA with ALSF primarily as a result of the provision in the placement agent agreement related to the 2019 PPM that required the Company to provide anti-dilution protection to the placement agent, certain of its related parties and the investors in the Private Placement but not the Company's other shareholders in the event that MCKEA were to convert its Series A Preferred Stock into Common Stock. ALSF and MCKEA are related parties, so the Company believes that it was fair and reasonable to permit ALSF to acquire shares of Common Stock for the same purchase price paid by the investors in the 2019 PPM in light of the constraints imposed on MCKEA's ability to convert its shares of Series A Preferred Stock as the Company's other shareholders would be harmed to some degree if MCKEA were to convert its Series A Preferred Stock.

Further, the additional funds that would be received by the Company from ALSF do not include any cash or equity based fees and are therefore far less expensive for the Company and less dilutive to its shareholders than funds received from the 2019 Offering. Finally, the term of the Note was intended to approximate the timing of when additional funds would be required by the Company, based on the assumption that a portion of the purchase would be funded throughout the term of the Note.

To the best of our knowledge, from inception to our most recent fiscal year end on April 30, 2020, 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 $15,344, or one percent of the average total assets at year-end for the last two completed fiscal years, 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.

INDEX TO FINANCIAL STATEMENTS
ALZAMEND NEURO, INC.

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, 2020 and 2019, 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, 2020 and 2019, 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, 2020, and does not have sufficient working capital at April 30, 2020 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, 2020

ALZAMEND NEURO, INC.
Balance Sheets

	April 30, 2020	April 30, 2019
ASSETS		
CURRENT ASSETS		
Cash	$ 90,285	$ 42,606
Note receivable, related party, net	100,915	205,915
Prepaid expenses and other current assets	1,622,815	1,252,396
TOTAL CURRENT ASSETS	1,814,015	1,500,917
TOTAL ASSETS	$ 1,814,015	$ 1,500,917
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 929,639	$ 1,104,669
Related party payable	62,667	79,333
TOTAL CURRENT LIABILITIES	992,306	1,184,002
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY		
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, 2020 and 2019, respectively	75	75
Common stock, $0.0001 par value: 300,000,000 shares authorized; 64,762,858 and 61,878,465 shares issued and outstanding as of April 30, 2020 and 2019, respectively	6,476	6,188
Additional paid-in capital	27,584,227	22,686,285
Note receivable for common stock – related party	(14,983,200)	(15,000,000)
Accumulated deficit	(11,785,869)	(7,375,633)
TOTAL STOCKHOLDERS' EQUITY	821,709	316,915
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,814,015	$ 1,500,917

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

ALZAMEND NEURO, INC.
Statements of Operations

	For the Year Ended April 30,	
	2020	**2019**
OPERATING EXPENSES		
Research and development	$ 1,069,418	$ 3,700,083
General and administrative	3,354,743	1,308,800
Total operating expenses	4,424,161	5,008,883
Loss from operations	(4,424,161)	(5,008,883)
OTHER INCOME (EXPENSE), NET		
Interest income - related party	13,925	146,387
Total other income (expense), net	13,925	146,387
NET LOSS	$ (4,410,236)	$ (4,862,496)
Basic and diluted net loss per common share	$ (0.06)	$ (0.08)
Basic and diluted weighted average common shares outstanding	71,253,580	58,843,040

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

ALZAMEND NEURO, INC.
Statements of Cash Flows

	For the Year Ended April 30, 2020	2019
Cash flows from operating activities:		
Net loss	$ (4,410,236)	$ (4,862,496)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of original issue discount on notes receivable – related party	-	(36,667)
Issuance of common stock for license fees	-	2,227,923
Stock-based compensation to employees and consultants	1,801,516	396,170
Non-cash consulting expense from issuance of common stock	453,724	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(15,764)	215,289
Accounts payable and accrued expenses	(175,030)	1,014,581
Net cash used in operating activities	(2,345,790)	(1,045,200)
Cash flows from investing activities:		
Loans to related party	-	(558,000)
Proceeds from repayments of notes receivable - related party	105,000	792,085
Net cash provided by investing activities	105,000	234,085
Cash flows from financing activities:		
Proceeds for issuance of common stock and warrants, net	2,288,335	236,023
Advances from related party payable	(16,666)	72,697
Proceeds from note receivable for common stock – related party	16,800	-
Net cash provided by financing activities	2,288,469	308,720
Net increase (decrease) in cash	47,679	(502,395)
Cash at beginning of period	42,606	545,001
Cash at end of period	$ 90,285	$ 42,606
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
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, 2020 and April 30, 2019

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Note Receivable for Common Stock -	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Related Party	Deficit	Total
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 and warrants	-	-	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	750,000	75	61,878,465	6,188	22,686,285	(15,000,000)	(7,375,633)	316,915
Issuance of common stock and warrants, net	-	-	2,284,393	228	2,288,107	-	-	2,288,335
Stock-based compensation to employees and consultants	-	-	-	-	1,801,516	-	-	1,801,516
Proceeds from note receivable – related party for common stock	-	-	-	-	-	16,800	-	16,800
Issuance of common stock for services	-	-	600,000	60	808,319	-	-	808,379
Net loss	-	-	-	-	-	-	(4,410,236)	(4,410,236)
BALANCES, April 30, 2020	750,000	$ 75	64,762,858	$ 6,476	$ 27,584,227	$ (14,983,200)	$ (11,785,869)	$ 821,709

The accompanying notes are an integral part of these 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, 2020, the Company had cash of $90,285 and an accumulated deficit of $11,785,869. The Company has incurred recurring losses and for the year ended April 30, 2020, such losses totaled $4,410,236. In the past, the Company has financed its operations principally through issuances of promissory notes and equity securities. During the year ended April 30, 2020, the Company continued to obtain additional equity 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, 2020, 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 (the "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, 2020 and 2019, the Company had no cash equivalents.

Fair Value of Financial Instruments

Our financial instruments are accounts payable. 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, 2020, 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 ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, ("ASU 2018-07"). Equity-classified nonemployee share based payment awards are measured at the grant date. The probability of satisfying performance condition is considered. 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, 2020 and 2019.

Since the effects of other 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 that has been excluded from the fully diluted calculation:

	For the Year Ended April 30,	
	2020	**2019**
Series A convertible preferred stock	15,000,000	15,000,000
Stock options (1)	16,175,000	8,210,000
Warrants	6,652,135	5,584,172
	37,827,135	28,794,172

(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 adopted this standard on May 1, 2019. The adoption of this standard did not have a material impact on the Company's 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 during 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. The adoption of this standard did not have a material impact on the Company's financial position or results of operations.

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. The balance outstanding on the AVLP Note as of April 30, 2020, was $100,915. Subsequent to year end, during the month of August 2020, the principal and accrued interest on the AVLP Note was paid in full.

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, 2020, the Company recorded contractual interest income from the stated interest rate of $13,925. 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.

On April 30, 2019, the Company and Ault Life Sciences Fund, LLC ("ALSF") 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 non-interest bearing note receivable with a 12-month term from ALSF, a related party. In November 2019, the term of the note receivable was extended to December 31, 2020. 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, 2020	April 30, 2019
Prepaid consulting fees	$ 1,513,602	$ 1,151,667
Interest receivable	77,153	63,229
Other prepaid expenses	15,850	21,290
Other receivables	16,210	16,210
Total prepaid expenses and other current assets	$ 1,622,815	$ 1,252,396

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, 2020 and 2019, the Company did not recognize any income tax benefit as a result of its net loss. The table below shows the balances for the deferred income tax assets and liabilities as of the date indicated.

	April 30, 2020	April 30, 2019
Deferred income tax asset:		
Net operating loss carryover	$ 2,333,201	$ 1,541,317
Other temporary differences	511,093	120,739
Total deferred tax asset	2,844,294	1,662,056
Valuation allowance	(2,844,294)	(1,662,056)
Deferred income tax asset, net of allowance	$ -	$ -

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

	For the Year Ended April 30, 2020	2019
Federal and State		
Current	$ -	$ -
Deferred	(2,844,294)	(1,662,056)
Valuation allowance	2,844,294	1,662,056
Income tax provision (benefit)	$ -	$ -

During the years ended April 30, 2020 and 2019, the Company did not recognize income tax expense. Our effective tax rate was 0% for the years ended April 30, 2020 and 2019. 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:

	For the Year Ended April 30, 2020	2019
Tax benefit at U.S. Federal statutory tax rate	-21.0%	-21.0%
Increase (decrease) in tax rate resulting from:		
Allowance against deferred tax assets	20.9%	20.9%
Nondeductible meals & entertainment expense and other	0.1%	0.1%
Taxes in respect of prior years	-	-
Changes in federal tax rate	-	-
Effective tax rate	0.0%	0.0%

At April 30, 2019, the Company had total domestic Federal net operating loss carryovers of approximately $11,110,482 available to offset future taxable income. Federal net operating loss carryovers (“NOLs”) expire beginning in 2026. 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, 2020 the valuation allowance has increased by $1,268,652.

The 2016 through 2020 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 five 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, 2020 and 2019, and changes during the years ended are as follows:

		Outstanding Options			
	Shares Available for Grant	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
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 cancelled/forfeited	35,000	(35,000)	$ 1.0000		
Options granted	(3,750,000)	3,750,000	$ 1.4267		
Balance at April 30, 2020	575,000	19,425,000	$ 0.6964	6.89	$ 15,609,500
Options vested and expected to vest at April 30, 2019		17,425,000	$ 0.6616	7.45	$ 14,609,500
Options exercisable at April 30, 2019		10,424,452	$ 0.3053	6.60	$ 12,454,020

The aggregate intrinsic value in the table above represents the total pretax estimated intrinsic value (i.e., the difference between the estimated fair value price of $1.50 per share 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, 2020 and 2019.

Stock options granted to employees and consultants

The estimated fair value of stock options granted to employees and consultants during the years ended April 30, 2020 and 2019, were calculated using the Black-Scholes option-pricing model using the following assumptions:

	For the Year Ended April 30,	
	2020	2019
Expected term (in years)	2.50 - 6.25	3.00 - 6.25
Volatility	65.80% - 72.35%	83.40%
Risk-free interest rate	1.52% - 2.36%	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 under the Plan 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, 2020, 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.

On November 26, 2019, the Board of Directors granted 4,250,000 performance- and market-contingent awards to certain key employees and a director. These grants were made outside of the Plan. These awards have an exercise price of $1.50 per share. These awards have multiple separate market triggers for vesting based upon either (i) the successful achievement of stepped target closing prices on a national securities exchange for 90 consecutive trading days later than 180 days after the Company's initial public offering for its common stock, or (ii) stepped target prices for a change in control transaction. The target prices range from $15 per share to $40 per share. In the event any the stock price milestones are not achieved within three years, the unvested portion of the performance options will be reduced by 25%. Due to the significant risks and uncertainties associated with achieving the market-contingent awards, through April 30, 2020, 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 uplisting agreement compensation

Pursuant to the Uplisting Agreement, discussed below, the Company issued to the Advisor 500,000 shares of Common Stock, valued at the $1.3668 estimated grant date fair value of the stock on the July 5, 2019 date of issuance. The stock compensation expense will be recognized over the two-year term of the agreement.

Stock issued for placement agent compensation

Upon the initial closing of the 2019 PPM, defined below, the Company issued to the Placement Agent 500,000 shares of Common Stock valued at the $1.3668 estimated grant date fair value of the stock on the August 30, 2019 date of issuance. The consideration was considered to be a cost of the equity offering, and accordingly, was netted against offering proceeds within additional paid in capital.

Stock issued for license fees

Pursuant to the terms of 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.

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,	
	2020	2019
Research and development	$ 309,499	$ 2,227,923
General and administrative	1,945,741	396,170
Total	$ 2,255,240	$ 2,624,093

As of April 30, 2020, total unamortized stock-based compensation expense related to unvested employee and non-employee awards that are expected to vest was $6.0 million. The weighted-average period over which such stock-based compensation expense will be recognized is approximately 2.6 years.

8. WARRANTS

In conjunction with a private offering of securities between June 25, 2019 and October 31, 2019, the Company issued 878,358 warrants with an exercise price of $3.00 per share. In addition, the Company issued to the placement agent of the private offering 175,672 warrants to purchase a number of shares of Common Stock (the "Placement Agent Warrants"), a figure equal to ten percent (10%) of the number of shares of Common Stock sold in the private offering. The Placement Agent Warrants are exercisable for a period of five years after their date of issuance, have an exercise price of $1.75 per share and contain provisions pertaining to cashless exercise, standard anti-dilution protection and piggyback registration rights. The grant date fair value of the Placement Agent Warrants was $95,467 and was recorded within additional paid-in capital. The estimated fair value of the Placement Agent Warrants, was calculated using the Black-Scholes option-pricing model using the following assumptions:

	For the Year Ended April 30, 2020
Risk-fee interest rate	1.52%
Expected term (in years)	2.5
Volatility	66%
Dividend yield	--

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

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:

	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 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, 2020:

Outstanding				Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.00	500,000	3.8	$1.00	108,333	$1.00
$1.20	5,500	0.3	$1.20	4,888	$1.20
$1.75	175,772	4.5	$1.75	14,647	$1.75
$3.00	5,970,863	3.9	$3.00	1,126,397	$3.00
$1.00 - $3.00	6,652,135	4.3	$2.82	1,254,265	$2.81

9. OTHER RELATED PARTY TRANSACTIONS

On May 1, 2016, we entered into a Management Services Agreement ("**MSA**") with Avalanche, a related party. The Company's directors, Messrs. Ault, Horne and Mansour are directors of Avalanche. Further, MCKEA is the majority member of Philou Ventures, LLC, which is the controlling shareholder of Avalanche. 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. 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 year ended April 30, 2019 we recognized $160,000 in management fees. At April 30, 2020 and April 30, 2019, $58,567 and $75,000, respectively, was included within related party payable on our balance sheet. The MSA expired on December 31, 2018.

In December 2018, we entered into a consulting agreement with Mr. Horne to provide 12 months of CFO transition consulting services for $50,000.

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 would provide consulting services to MCKEA 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 5,000,000 shares of Common Stock were transferred by MCKEA to Spartan on January 31, 2018.

The amount due at April 30, 2019 to MCKEA and our officers for reimbursement of expenses paid and incurred by these related parties was $6,736. The amount is included within related party payable on our balance sheet.

10. 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, 2020, 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 "2017 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 2017 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 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 2017 Offering.

2019 Placement Agreement

Between June 25, 2019 and October 31, 2019, the Company entered into subscription agreements for the purchase of 1,756,726 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 1,756,726 units represents 1,756,726 shares of Common Stock and 878,363 warrants with an exercise price of $3.00 per share for an aggregate purchase price of $2,635,089, or $1.50 per share. The 2019 Offering was conducted pursuant to the terms of a Confidential Private Placement Memorandum dated June 12, 2019 (the "2019 PPM"). As of April 30, 2019, in conjunction with the 2019 PPM, the Company incurred $395,263 in placement fees resulting in net proceeds to the Company of $2,239,826.

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 PPM the Company paid to the Placement Agent a non-refundable fee of Twenty-Five Thousand Dollars ($25,000) and issued to the Placement Agent 500,000 shares of Common Stock.

Further, the Company has issued 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 PPM. The Placement Agent Warrants are exercisable for a period of five (5) years after their date of issuance, have an exercise price of $1.75 per share and contain provisions pertaining to cashless exercise, standard anti-dilution protection and piggyback registration rights.

Use of Proceeds:
The Company applied the net proceeds from the 2019 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 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 the 2019 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 PPM 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 PPM.

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 PPM, 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 PPM 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 PPM 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.

11. 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:

Payment	Due Date	Event
$ 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 clinical 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, 2020. 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 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, the Company is required to pay milestone payments on the due dates to Licensor for the license of the technology, as follows:

Payment	Due Date	Event
$ 50,000	Completed September 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.

12. SUBSEQUENT EVENTS

In accordance with FASB ASC 855-10, the Company has analyzed its operations subsequent to April 30, 2020 and has determined that it does not have any material subsequent events to disclose in these financial statements except for the following.

On June 10, 2020, the Company obtained two additional royalty-bearing, exclusive worldwide licenses from the Licensor to a therapy known as LiProSal™. One of the additional licenses is for the treatment of neurodegenerative diseases excluding Alzheimer's Disease and the other is for the treatment of psychiatric diseases/disorders. LiProSal™ is an ionic cocrystal of lithium. 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 10, 2020, (the "LiProSal ™ License Agreements") with the Licensor and the University. In addition, a royalty payment of 3% is required on net sales of products developed from the licensed technology. For the two additional LiProSal ™ licenses, in the aggregate, the Company is are required to pay initial license fees of $20,000 no later than June 10, 2021. Additionally, the Company is required to pay milestone payments on the due dates to Licensor for the license of the technology, as follows:

Payment	Due Date	Event
$ 30,000	Completed September 2019	Pre-IND meeting
$ 50,000	October 30, 2020	IND application filing
$ 150,000	12 months from IND filing date	Upon first dosing of patient in a clinical trial
$ 400,000	12 months from first patient dosing	Upon Completion of first clinical trial
$ 1,000,000	36 months from completion of the first Phase II clinical trial	Upon first patient treated in a Phase III clinical trial
$ 8,000,000	8 years from the effective date of the agreement	First commercial sale

In August 2020, the Company entered into a Securities Purchase Agreement with an institutional investor to sell a Convertible Promissory Note of the Company, in the aggregate principal amount of $275,000 for a purchase price of $250,000 and issue a 5-year warrant to purchase 91,667 of shares of its Common Stock. The Convertible Promissory Note bears interest at 8% per annum, which principal and all accrued and unpaid interest are due six months from the date of issuance. The principal and interest earned on the Convertible Promissory Note may be converted into shares of the Company's Common Stock at $1.50 per share. The exercise price of the warrant is $3.00 per share.

During the month of August 2020, the principal and accrued interest on the AVLP Note was paid in full.

ITEM 8. EXHIBITS

Index to Exhibits

Exhibit No.	Exhibit Description
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(Incorporated by reference to Exhibit 6.5 of Form 1-K filed with the Securities and Exchange Commission on August 28, 2019).
6.6	Standard Exclusive License Agreement with Sublicensing Terms Number LIC19050 with the University of South Florida Research Foundation, Inc., dated June 10, 2020. Filed herewith.
6.7	Standard Exclusive License Agreement with Sublicensing Terms Number LIC19051 with the University of South Florida Research Foundation, Inc., dated June 10, 2020. 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, 2020

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, 2020

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

STANDARD EXCLUSIVE LICENSE AGREEMENT
WITH SUBLICENSING TERMS

Agreement # LIC19050

This Agreement is made effective *nunc pro tunc* November 1, 2019, (the "Effective Date") by and between the University of South Florida Research Foundation, Inc. (hereinafter called " Licensor"), a nonstock, nonprofit Florida corporation, under Chapter 617 Florida Statutes, and a direct support organization of the University of South Florida ("University") pursuant to section 1004.28 Florida Statutes and Alzamend Neuro Inc. (hereinafter called "Licensee"), a small corporation organized and existing under the laws of Delaware;

WHEREAS, University is the owner of certain inventions described in the "Licensed Patents" defined below (University Reference # 12B100);

WHEREAS, Licensor is the exclusive licensee of the Licensed Patents, and Licensor is willing to grant a license to Licensee under the Licensed Patents and Licensee desires a license to the Licensed Patents;

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

Section 1 **Definitions**

1.1 "Affiliate" means: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the Licensee or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the Licensee or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of Licensee or (d) any entity in which any officer or employee is also an officer or employee of Licensee or any person who is an officer or employee of Licensee or (e) any other relationship as in fact, constitutes actual control.

1.2 "Development Plan" means the written report summarizing the development activities that are to be undertaken by the Licensee to bring Licensed Products and/or Licensed Processes to the market. The Development Plan is attached as Appendix A.

1.3 "Development Report" means a written account of Licensee's progress under the Development Plan having at least the information specified on Appendix B to this Agreement, and shall be sent to the address specified on Appendix B .

1.4 "Investigator" means Drs. Roland (Doug) Shytle, Michael Zaworotko, Adam Smith and Naga Duggirala, while employed by Licensor.

1.5 "First Commercial Sale" means the first commercial sale, lease or other transfer, practice or disposition of any Licensed Product or Licensed Process for value in any country by Licensee or by a Sublicensee to a third party that is not a Licensee Affiliate or a Sublicensee.

1.6 "Know-How" means unpatented technology and/or information that was developed by the Investigator, including without limitation methods, processes, techniques, compounds, cell lines, materials, sequences, drawings, indications, data, results of tests, or studies, plans, and expertise, whether patentable or not, which relates specifically to the Licensed Patents and existing on the date hereof, only to the extent wholly owned and controlled by Licensor, except that, Know-How shall not include the Licensed Patents.

1.7 "Licensed Field" means the field of LiProSal (lithium co-crystal) for the treatment of Neurodegenerative Diseases excluding Alzheimer's Disease.

1.8 "Licensed Patents" means all of the following Licensor intellectual property:

1.8.1 the patent(s)/patent application(s) identified on Schedule 1.8 hereto;

1.8.2 any and all United States and foreign patent applications claiming priority to any of the patent(s) and patent application(s) identified on Schedule 1 hereto (except that in the case of continuation-in-part application(s), only to the extent that the subject matter claimed in such continuation-in-part application(s) is supported under 35 U.S.C 112 in the patent(s)/patent application(s) identified on Schedule 1 hereto); and

1.8.3 any and all patents issuing from the patent applications identified in section 1.8.1 and 1.8.2, including, but not limited to, letters patents, patents of addition, reissues, re- examinations, extensions, restorations, and supplementary protection certificates;

all to the extent owned or controlled by Licensor.

1.9 "Licensed Product" and "Licensed Process" means:

1.9.1 In the case of a Licensed Product, any product or part thereof, on a country-by-country basis, that:
(a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which such product is made, used, imported or sold; or
(b) is manufactured by using a process that is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which any such process is used or in which any such product is used, imported, or sold; or
(c) incorporates, utilizes, or was developed utilizing, Know-How or that is manufactured using Know-How or using a process developed using Know-How.

1.9.2 In the case of a Licensed Process, any process, on a country-by-country basis, that:
(a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents in any country in which such process is practiced; or
(b) incorporates, utilizes, or was developed utilizing, Know-How.

1.10 "Licensed Territory" means worldwide.

1.11 "Net Sales" means the total dollar amount invoiced on sales of Licensed Product and/or Licensed Processes by Licensee, Sublicensee or Affiliates. Total amount invoiced may include only promotional discounts allowed in amounts customary in the trade.

1.12 "Patent Challenge" means a challenge to the validity, patentability, enforceability and/or non-infringement of any of the Licensed Patents or otherwise opposing any of the Licensed Patents.

1.13 "Sublicense" means, an agreement or series of related agreements to, directly or indirectly, sublicense, grant any other right with respect to, or agree not to assert, any right licensed to Licensee under this Agreement. An agreement that is described in this definition is a Sublicense whether or not it is called a "sublicense" and whether or not it is included in a stand-alone document or is part of series of agreements establishing a broader collaboration, development, asset purchase, joint venture agreement or other arrangement.

1.14 "Sublicensee" means any third party to whom Licensee grants a Sublicense.

Section 2 **Grant**

2.1 License.

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

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

2.2 Sublicense.

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

2.2.2 Licensee shall provide Licensor with an unredacted copy of each Sublicense agreement (and in the case of a series of related agreements, all such related agreements) and any subsequent amendments which transfers intellectual property rights granted hereunder, at least thirty (30) days prior to the execution of the Sublicense agreement. Licensee shall also provide Licensor with copies of any Sublicensee milestone and royalty reports.

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

Section 3 **Due Diligence**

3.1 Development.

3.1.1 Licensee agrees to and warrants that:

(a) it has, or will obtain, the expertise necessary to independently evaluate the inventions of the Licensed Patents and Know-How;

(b) it will actively and diligently pursue the Development Plan, (see Appendix A) to the end that the inventions of the Licensed Patents will be utilized to provide Licensed Products and/or Licensed Processes for sale in the retail market within the Licensed Field;

(c) it will diligently develop markets for Licensed Products and Licensed Processes;

(d) and, until the date of First Commercial Sale of Licensed Products or Licensed Processes, it will supply Licensor with a written Development Report annually within fifteen (15) days after the end of the calendar year (see Appendix B).

3.1.2 Licensee agrees that the First Commercial Sale of products to the retail customer shall occur on or before July 1, 2027 or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3 hereto. In addition, Licensee will meet the milestones shown in Appendix D or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3. Licensee will notify Licensor in writing as each milestone is met.

3.1.3 Upon written request by Licensee to negotiate extensions of any milestones or due dates set forth in Appendix D, such request to be received by Licensor no less than ninety (90) days prior to any of the due dates subject of such request, set forth in this Section 3.1.3, such request fully describing Licensee's diligent efforts to achieve the milestone required to be met by such due date, Licensor shall consider in good faith such requests. Upon granting such request, Licensor and Licensee shall negotiate such extensions in good faith.

3.1.4 University's policies may require approval of clinical trials involving technology invented by Licensor. Accordingly, Licensee will notify Licensor prior to commencing any clinical trials at the University's facility or any affiliated medical facilities.

3.1.5 Every year Licensor is required to report on statistics that are relevant to growth of businesses in Florida. On January 31 and July 31 of each year, Licensee shall provide to Licensor a report that includes: the current number of employees in Florida, the total number of employees, information about whether Licensee has gone public or been acquired, detail on the amount and sources of funding, any new products that have been introduced to the market, the number of employees who are University graduates, and the number of University interns for the period since the last report was received. This specific information will be held in confidence and provided in the aggregate. No information obtained under this Section 3.1.5 will be identified as being connected with Licensee absent agreement of the Licensee.

Section 4 **Payments**

4.1 License Issue Fee.

Licensee agrees to pay Licensor a License Issue Fee of ten thousand Dollars ($10,000.00) due on the first anniversary of the Effective Date.

4.2 Intentionally Omitted

4.3 Royalty.

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

(i) three percent (3%) for Net Sales of Licensed Products, for each product, on a country- by-country basis, as defined by Sections 1.7.1 (a), and 1.7.1(b); and

(ii) three percent (3%) for Net Sales of Licensed Processes, for each process, on a country-by-country basis, as defined by Section 1.7.2 (a); and

(iii) two percent (2%) for Net Sales of Licensed Products and Licensed Processes sold during a period of regulatory exclusivity as defined by the appropriate regulatory body for such Licensed Product or Licensed Process in the country in which such Licensed Product or Licensed Process is sold.

Royalties shall be payable until the later, on a country-by-country basis, of (i) the expiration of the last-to-expire Licensed Patents, (ii) the expiration of any applicable regulatory exclusivity period in such country, and (iii) ten (10) years from the First Commercial Sale of a Licensed Product or Licensed Process in such country in which the Licensed Product or Licensed Process is sold.

4.4 Other Payments.

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

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

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

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

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

Licensee is entering into multiple license agreements with Licensor related to USF Technology 12B100, also referred to as the LiProSal product. For the avoidance of doubt, it is understood and agreed that only one of each such milestone payments shall be payable as between LIC19050 and LIC19051 ..

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

4.5 Accounting for Payments.

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

4.5.2 Any amounts which remain unpaid after the date they are due toLicensor shall accrue interest from the due date at the rate of 1.5% per month. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. Licensee shall also be responsible for repayment to Licensor of any attorney, collection agency, or other out-of-pocket Licensor expenses required to collect overdue payments due under this Section 4 or any other applicable Section of this Agreement.

4.5.3 Except as otherwise directed, all amounts owing to Licensor under this Agreement shall be paid in U.S. dollars to Licensor at the following address:

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

4.5.4 A certified full accounting statement showing how any amounts payable to Licensor under Section 4 have been calculated shall be submitted to Licensor on the date of each such payment. In addition to being certified, such accounting statements shall contain a written representation signed by an executive officer of Licensee that states that the statements are true, accurate, and fairly represent all amounts payable to Licensor pursuant to this Agreement. For earned royalties, such accounting shall be on a per- country and product line, model or trade name basis and shall be summarized on the form shown in Appendix C – Licensor Royalty Report of this Agreement. For earned royalties, in the event no payment is owed to Licensor because the amount of minimum royalties paid has not been exceeded or otherwise, an accounting demonstrating that fact shall be supplied to Licensor.

4.5.5 Licensor is exempt from paying income taxes under U.S. law. Therefore, all payments due under this Agreement shall be made without deduction for taxes, assessments, or other charges of any kind which may be imposed on Licensor by any government outside of the United States or any political subdivision of such government with respect to any amounts payable to Licensor pursuant to this Agreement. All such taxes, assessments, or other charges shall be assumed by Licensee.

Section 5 **Certain Warranties and Disclaimers of Licensor**

5.1 Licensor warrants that, except as otherwise provided under Section 17.1 of this Agreement with respect to U.S. Government interests, it is the owner or exclusive licensee of the Licensed Patents or otherwise has the right to grant the licenses granted to Licensee in this Agreement. However, nothing in this Agreement shall be construed as:

(a) a warranty or representation by Licensor as to the validity or scope of any right included in the Licensed Patents;
(b) a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of third parties;
(c) an obligation to bring or prosecute actions or suits against third parties for infringement of Licensed Patents;
(d) an obligation to furnish any services other than those specified in this Agreement; or
(e) a warranty or representation by Licensor that it will not grant licenses to others to make, use or sell products not covered by the claims of the Licensed Patents which may be similar and/or compete with products made or sold by Licensee.

5.2 Licensee warrants that it has the power and authority to enter into and perform its obligations under this Agreement and that the execution of this Agreement by it has been duly and validly authorized by all necessary corporate action and its obligations under this Agreement are valid and binding and enforceable against it in accordance with their terms.

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

Section 6 **Record Keeping**

6.1 Licensee and its Sublicensee(s) shall keep books and records sufficient to verify the accuracy and completeness of Licensee's and its Sublicensee(s)'s accounting referred to above, including without limitation, inventory, purchase and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to the Licensed Products and/or Licensed Processes. Such books and records shall be preserved for a period not less than six years after they are created or as required by federal law, both during and after the term of this Agreement.

6.2 Licensee and its Sublicensee(s) shall take all steps necessary so that Licensor may, within thirty (30) days of its written request, audit, review and/or copy all of the books and records at a single U.S. location to verify the accuracy of Licensee's and its Sublicensee(s)'s accounting. Such review may be performed by any authorized employees of Licensor as well as by any attorneys and/or accountants designated by Licensor, upon reasonable notice and during regular business hours. If a deficiency with regard to any payment hereunder is determined, Licensee and its Sublicensee(s) shall pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4.5.1. If a royalty payment deficiency for a calendar year exceeds three percent (3%) of the royalties paid for that year, then Licensee and its Sublicensee(s) shall be responsible for paying Licensor's out-of-pocket expenses incurred with respect to such review.

6.3 At any time during the term of this Agreement, Licensor may request in writing that Licensee verify the calculation of any past payments owed to Licensor through the means of a self-audit. Within ninety (90) days of the request, Licensee shall complete a self-audit of its books and records to verify the accuracy and completeness of the payments owed. Within thirty (30) days of the completion of the self-audit, Licensee shall submit to Licensor a report detailing the findings of the self-audit and the manner in which it was conducted in order to verify the accuracy and completeness of the payments owed. If Licensee has determined through its self- audit that there is any payment deficiency, Licensee shall pay Licensor the deficiency along with applicable interest under Section 4.5.1 with the submission of the self-audit report to Licensor.

Section 7 **Patent Prosecution**

7.1 Licensor shall be solely responsible for preparing, filing, prosecuting and maintaining the Licensed Patents using counsel of its choice. Licensor shall provide Licensee with copies of all documents sent to and received from the United States Patent and Trademark Office and foreign patent offices relating to Licensed Patents. Licensee agrees to keep such information confidential. Licensor shall provide Licensee with a reasonable opportunity to comment on the preparation, prosecution and maintenance of the Licensed Patents and will consider Licensee's comments in good faith.

7.2 Intentionally Omitted

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

Section 8 **Infringement and Invalidity**

8.1 Licensee shall inform Licensor promptly in writing of any alleged infringement of the Licensed Patents by a third party and of any available evidence thereof.

8.2 During the term of this Agreement, Licensor shall have the right, but shall not be obligated, to prosecute at its own expense any such infringements of the Licensed Patents. If Licensor prosecutes any such infringement, Licensee agrees that Licensor may include Licensee as a co- plaintiff in any such suit, without expense to Licensee.

8.3 If within six (6) months after having been notified of any alleged infringement, Licensor shall have been unsuccessful in persuading the alleged infringer to desist and shall not have brought an infringement action against the alleged infringer, or if Licensor shall notify Licensee at any time prior thereto of its intention not to bring suit against the alleged infringer, then, and in those events only, Licensee shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents, and Licensee may, for such purposes, use the name of Licensor as party plaintiff. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Licensor, which consent shall not be unreasonably withheld. Licensee shall indemnify Licensor against any order for costs that may be made against Licensor in such proceedings.

8.4 In the event that a declaratory judgment action is brought against Licensor or Licensee by a third party alleging invalidity, unpatentability, unenforceability, or non-infringement of the Licensed Patents, Licensor, at its option, shall have the right within twenty (20) days after commencement of such action to take over the sole defense of the action at its own expense. If Licensor does not exercise this right, Licensee shall be responsible for the sole defense of the action at Licensee's sole expense, subject to Sections 8.5 and 8.6.

8.5 In the event that Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, Licensor shall have the right, but not the obligation, to voluntarily join such litigation, represented by its own counsel at its own expense. In the event that Licensor or Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by Licensor or Licensee for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of Licensor relating to the suit, and next toward reimbursement of any unreimbursed expenses and legal fees of Licensee relating to the suit. The balance remaining from any such recovery shall be divided equally between Licensee and Licensor.

8.6 In any suit in which either party is involved to enforce or defend the Licensed Patents pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

8.7 In the event Licensee, its Affiliate or Sublicensee brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor, unless and until Licensor terminates this Agreement pursuant to Section 9, Licensee shall continue to pay royalties and make other payments pursuant to this Agreement with respect to the contested Licensed Patent(s) as if such Patent Challenge were not underway until the contested Licensed Patent(s) is adjudicated invalid or unenforceable by a court of last resort. If at the end of such Patent Challenge any of the challenged Licensed Patents remain valid, then at Licensor's option, (i) all royalties and other payments due under this Agreement with respect to such Patent Rights will double or (ii) Licensor may terminate this Agreement if it has not already done so.

Section 9 **Term and Termination**

9.1 The term of this license shall begin on the Effective Date of this Agreement and continue until the later of the date that no Licensed Patent remains a pending application or an enforceable patent, or the date on which Licensee's obligation to pay royalties expires pursuant to Section 4.3 above.

9.2 Licensee may terminate this Agreement at any time by giving at least sixty (60) days written notice of such termination to Licensor. Such a notice shall be accompanied by a statement of the reasons for termination.

9.3 Licensor may terminate this Agreement if (a) Licensee (i) is delinquent on any report or payment; (ii) is not diligently developing and commercializing Licensed Products and Licensed Processes; (iii) misses a milestone described in Appendix D; (iv) is in breach of any provision; (v) provides any false report; (vi) goes into bankruptcy, liquidation or proposes having a receiver control any assets; (vii) violates any laws or regulations of applicable government entities; or (viii) shall cease to carry on its business pertaining to Licensed Patents; or (b) if payments of earned royalties under Section 4.3, once begun, cease for more than two (2) calendar quarters. Termination under this Section 9.3 will take effect 30 days after written notice by Licensor, unless Licensee remedies the problem in that 30-day period, except that termination under Section 9.3 (vi) will occur immediately and automatically upon the occurrence of the event and require no action by Licensor.

9.4 If Licensee or any of its Affiliates brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may immediately terminate this Agreement and/or the license granted hereunder. If a Sublicensee brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may send a written demand to Licensee to terminate such Sublicense. If Licensee fails to so terminate such Sublicense within forty-five (45) days after Licensor's demand, Licensor, at its option, may (i) elect to immediately terminate this Agreement and/or the license granted hereunder or (ii) to double all royalties and other payments due under this Agreement with respect to such Patent Rights.

9.5 If Licensee, any of its Affiliates or a Sublicensee (i) brings a Patent Challenge against Licensor or (ii) assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), and if Licensor does not choose to exercise its rights to terminate this Agreement pursuant to Section 9.4 then, in the event that such the Patent Challenge is successful, Licensee will have no right to recoup any consideration, including royalties, paid during the period of challenge. In the event that the Patent Challenge is unsuccessful, Licensee shall reimburse Licensor for all reasonable legal fees and expenses incurred in its defense against the Patent Challenge.

9.6 Licensor may immediately terminate this Agreement upon the occurrence of the second separate default by Licensee within any consecutive three-year period for failure to pay royalties, patent or any other expenses when due.

9.7 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Licensee shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination, and any minimum royalties shall be prorated as of the date of termination by the number of days elapsed in the applicable calendar year. Licensee may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that Licensee shall remain obligated to provide an accounting for and to pay running royalties thereon.

9.8 Licensee shall be obligated to deliver to Licensor, within ninety days of the date of termination of this agreement, complete and unredacted copies of all documentation prepared for or submitted for all regulatory approvals of Licensed Products or Licensed Processes.

Section 10 **Assignability**

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

Section 11 **Dispute Resolution Procedures**

11.1 Mandatory Procedures.

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

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

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

11.1.3 Not more than fifteen (15) days after the giving of such notice of issues, each party shall deliver to the other party a list of the names and addresses of at least three individuals, any one of whom would be acceptable as a neutral advisor in the dispute (the "Neutral Advisor") to the party delivering the list. Any individual proposed as a Neutral Advisor shall have experience in determining, mediating, evaluating, or trying intellectual property litigation and shall not be affiliated with the party that is proposing such individual.

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

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

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

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

11.2 Failure to Resolve Dispute.

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

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

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

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

Section 13 **Use of Names**

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

Section 14 **Miscellaneous**

14.1 This Agreement shall be construed in accordance with the internal laws of the State of Florida without regard to its conflicts of law principles.

14.2 The parties hereto are independent contractors and not joint venturers or partners.

14.3 Licensee shall ensure that it applies patent markings that meet all requirements of U.S. law, 35 U.S.C. §287, with respect to all Licensed Products subject to this Agreement.

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

14.5 Licensee shall not encumber or otherwise grant a security interest in any of the rights granted hereunder to any third party.

14.6 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Contract Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. Licensor neither represents that a license is or is not required or that, if required, it shall be issued.

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

14.8 Survival.

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

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

Section 15 **Notices**

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

15.1 All payments and royalty reports to: USF Research Foundation

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

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

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

15.2 If to Licensee:

Alzamend Neuro™, Inc.
3802 Spectrum Blvd., Suite 112C Tampa, FL 33612

Section 16 **Contract Formation and Authority**

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

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

16.2 Force Majeure.

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

Section 17 **United States Government Interests**

17.1 It is understood that the United States Government (through any of its agencies or otherwise) has funded research during the course of or under which any of the inventions of the Licensed Patents were conceived or made. The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §202-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the inventions of such Licensed Patents for governmental purposes. Any license granted to Licensee in this Agreement shall be subject to such right.

17.2 Licensee agrees that for Licensed Products covered by the Licensed Patents that are subject to the non-exclusive royalty-free license to the United States Government, said Licensed Products will be manufactured substantially in the United States. Licensee further agrees that it shall abide by all the requirements and limitations of U.S. Code, Title 35, Chapter 18, and implementing regulations thereof, for all patent applications and patents invented in whole or in part with federal money.

Section 18 **Confidentiality**

18.1 Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential and that is marked "confidential" by the disclosing party or that is confirmed in writing within ten (10) days after verbal disclosure (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, Sublicensees or agents. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section 18 shall extend for a period of five (5) years from termination or expiration of this Agreement.

Section 19 **University Rules and Regulations**

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

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

UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.

/s/ David Conrad Date: June 10, 2020
David Conrad, Director
Technology Transfer Office

ALZAMEND NEURO, INC.

/s/ Stephan Jackman Date: June 8, 2020
Stephan Jackman, CEO

ACKNOWLEDGED AND AGREED:

UNIVERSITY OF SOUTH FLORIDA BOARD OF TRUSTEES A PUBLIC BODY CORPORATE

/s/ Keith Anderson June 10, 2020
Keith Anderson, Director

INVENTOR

Dr. Roland (Doug) Shytle

SCHEDULE 1.8 – LICENSED PATENTS

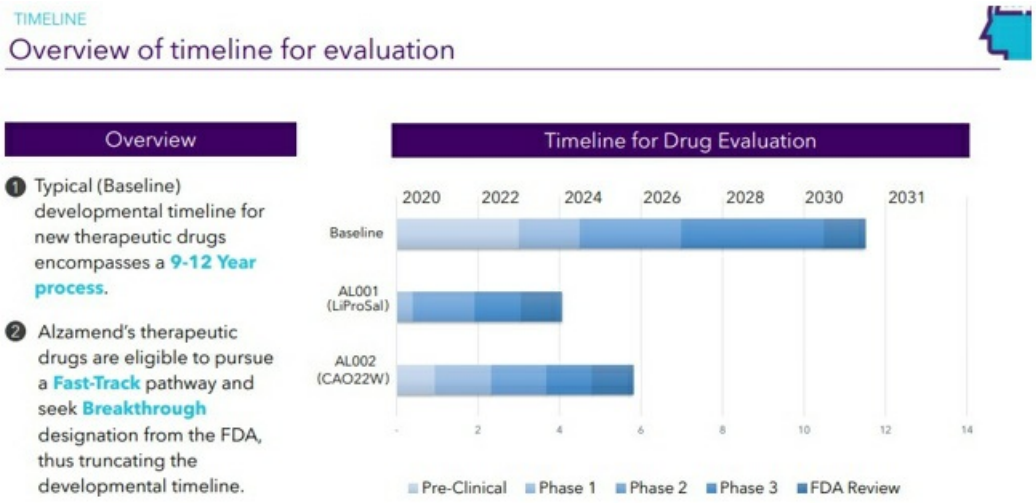
United States Patent No. 9,840,521, entitled “Organic Anion Lithium Ionic Cocrystal Compounds and Compositions”, filed 09/24/2015 and granted 12/12/2017.

Appendix A - Development Plan

I. Development Program

Development activities to be undertaken.

Continue with Reg A+ funding strategy already in place. See attached plan slide deck below that outlines fundraising and preclinical/clinical path:



COMPANY OVERVIEW

Overview of company goals and projects

Company history

Biotechnology company dedicated to:

- Researching, developing and commercializing **preventions**, **treatments and cures** for Alzheimer's
- Working on **two therapeutics** licensed from the **University of South Florida**, one of the top 20 institutions in the nation for patented research and their portfolio of proprietary solutions.

Current projects

AL001 (aka LiProSal): an ionic cocrystal of lithium that may greatly **reduce** or **eliminate** the **symptoms of agitation** and other endpoints for mild to moderate stage patients diagnosed with Alzheimer's.

AL002 (aka CAO22W): adjuvant-free therapeutic vaccine intended for use as a **treatment** or **prophylactic** for patients diagnosed with Alzheimer's.

GENERAL OVERVIEW

Overview of Alzheimer's disease

Key Statistics:

6th leading cause of death in the United States

Every 65 seconds someone in the United States develops Alzheimer's Disease

14 million people are projected to be living with Alzheimer's by 2050

1-in-10 Americans over the age of 65 are estimated to be afflicted with Alzheimer's

Alzheimer's Disease:

Alzheimer's disease is an irreversible, progressiv brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks. In most people with Alzheimer's, symptoms first appear in their early to mid-60's. Estimates vary, but experts suggest that more than 5.8 million Americans may have Alzheimer's, considered by many as "the most feared" disease.

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

GENERAL SCIENTIFIC OVERVIEW

Overview of our science

Therapeutic Drug	Synopsis	Strength	Status
AL001	• Use of patented Ionic Cocrystal (ICC) technology delivering a therapeutic combination of Lithium, Proline, and Salicylate • Lithium as a treatment of agitation and other possible symptoms in patients with indication of Alzheimer's disease • Other potential indications: Dementia, Parkinson's Disease, ALS, Depression, Bi-Polar Disorder, Mania, Post Traumatic Stress Disorder (PTSD), Suicidality, etc.	• Exclusive license for Cocrystal delivery system to treat Alzheimer's disease • Eligible for "breakthrough therapy" designation from FDA • Seeking a 505(b)(2) clinical trial pathway from FDA • Formulation may importantly expand the range of therapeutic categories amenable to lithium treatments, with enhanced safety • Has the potential of becoming the replacement for all lithium therapy on the market	• Filed Pre-IND in Q3 2019 • Filing IND in Q4 2020 • Commencing Phase 1 human clinical trials in Q4 2020
AL002	• 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. • Also seeks to mitigate adverse reactions from a patient's immunological system experienced during pre-clinical trials including the highly publicized Elan study (AN-1972)	• Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of AD • Difficult to manufacture and hence not easily replicated by competitors • Eligible for "breakthrough therapy" status via FDA • Antibody responses induced after one inoculation (Pre-Clinical) and lasted for 4 months • Inflammation cytokines like IL1 and TNF.alpha, which are considered being related to inflammation didn't increase with antibody level increase	• Completing pre-clinical studies Q2 2020 • Filing Pre-IND in Q3 2020 • Filing IND in Q4 2020 • Commencing Phase 1 human clinical trials in Q4 2020

ALZAMEND NEURO

Overview of AL001 (aka LiProSal or LISPRO)

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

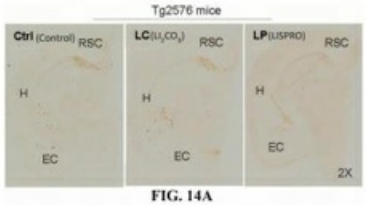


FIG. 14A

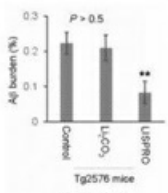


FIG. 14B

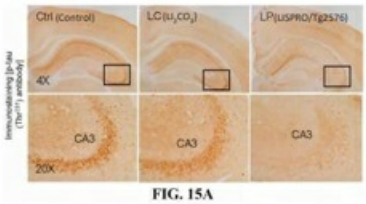


FIG. 15A

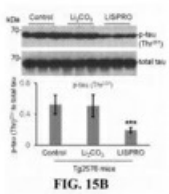
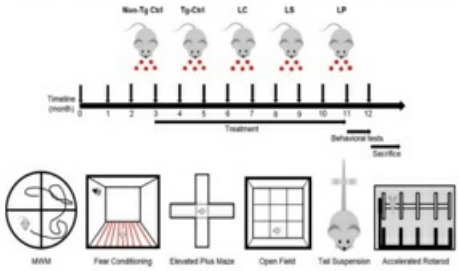


FIG. 15B

ALZAMEND NEURO

Overview of AL001 (aka LiProSal or LISPRO)



- With the goal of improving lithium's therapeutic profile, we investigated the safety, pharmacokinetics, and therapeutic efficacy of LiProSal™ (LP), compared with lithium carbonate (LC) and lithium salicylate (LS) across a host of preclinical models of AD.
- Female APPSWE/PS1dE9 mice at 4 months of age were orally treated with LP, LS, or LC for 9 months followed by determination of body weight, growth of internal organs, and cognitive and non-cognitive behavior.
- Untreated age-matched non-transgenic littermates served as wild-type (WT) controls.

The Results

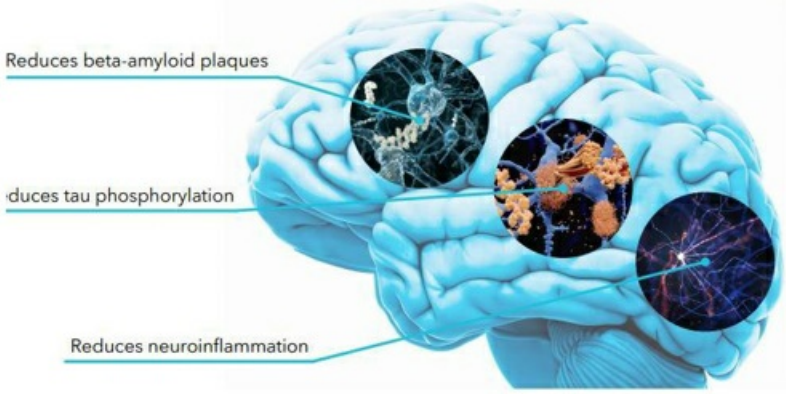
- No significant differences in body weight, brain, heart, lung, spleen, liver or kidney were found between lithium treated- and untreated APPSWE/PS1dE9 cohorts.
- LP treatment **improved cognitive function**, as shown by lower escape latency during training and probe trial of the Morris water maze (MWM) test and longer contextual freezing time during the fear conditioning test.
- LP treatment also **reduced depression**, as assessed by tail suspension test, and irritability, as assessed by touch escape test.
- LP treatment afforded s**uperior protection against cognitive impairment** as determined by contextual fear conditioning test and irritability in comparison with LC or LS treatment.
- Chronic LP treatment **prevent cognitive deficits**, depression and irritability in female APPSWE/PS1dE9 mice, and is superior in improving associative learning and memory and irritability compared with lithium salicylate or carbonate treatments, supporting the potential of this lithium formulation for the treatment of AD.

ALZAMEND NEURO

Potential Impact of AL001

Arrests cognitive decline

Slows the progression of Alzheimer's disease



Improves brain health:

- **Increases** BDNF or brain-derived neurotrophic factor promoting neurogenesis
- **Reduces** the production of inflammatory cytokines
- **Inhibits** glycogen synthase kinase-3 beta (GSK3β)
- **Increases** docosahexaenoic acid (DHA) – an omega-3 fatty acid essential for brain development
- **Inhibits** microglial activation
- **Promotes** neuronal stem cell differentiation
- **Promotes** autophagy, clearing damaged cells

BUDGET DETAILS

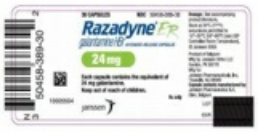
Overview of preliminary budgetary estimate

Category	2019	2020	2021	2022	2023	5-year Total
Phase 1 clinical trial*	$ -	$ 7,035,000	$ -	$ -	$ -	$ 7,035,000
Phase 2 clinical trial*	-	-	20,000,000	7,000,000	-	27,000,000
Phase 3 clinical trial*	-	-	30,000,000	40,000,000	40,000,000	110,000,000
License fees	280,000	400,000	2,425,000	1,000,000	-	4,105,000
Outsourced clinical services	767,000	706,000	475,000	570,000	684,000	3,202,000
SG&A expenses	963,000	3,200,000	2,655,000	2,826,000	3,014,000	12,658,000
Total	$ 2,010,000	$ 11,341,000	$ 55,555,000	$ 51,396,000	$ 43,698,000	$ 164,000,000

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

COMPETITIVE LANDSCAPE

Overview of Alzheimer's Disease drugs on the market



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

*Aricept - Eisai Co., Ltd. Third Quarter Financial Results (https://www.eisai.com/ir/library/settlement/pdf/e201BQ3_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).
*Thomson Reuters Report - (https://www.researchgate.net/publication/274930518_Spotlight_on_Alzheimers_disease_a_Thomson_Reuters_Pharma_Matters_report).

COMPETITIVE LANDSCAPE

Overview of AL001 commercial market evaluation

Potential annual revenue

Patient Population	Price per patient/yearly	10% Market Capture	20% Market Capture	30% Market Capture
16.2 Million - Depression	$2,400	$3.9 Billion	$7.8 Billion	$11.7 Billion
13.0 Million – PTSD	$4,100	$5.3 Billion	$10.6 Billion	$15.9 Billion
5.8 Million - Alzheimer	$3,000	$1.7 Billion	$3.5 Billion	$5.1 Billion
5.7 Million - Bipolar Disorder	$1,800	$1.0 Billion	$2.0 Billion	$3.0 Billion
Total 40.7 Million – Patient Population		$12 Billion	$24 Billion	$36 Billion

Medication cost per year for Depression: https://depression.informedchoices.ca/types-of-treatment/medication-treatment/cost-of-medication/
Medication cost per year for PTSD: https://www.marketwatch.com/story/what-ptsd-costs-families-2014-04-04
Medication cost per year for Alzheimer: https://www.takeda.com/siteassets/system/investors/report/quarterlyannouncements/fy2017/fy2017-full-year-results/qr2017_q4_d_en.pdf.
Medication cost per year for Bipolar Disorder: https://www.ncbi.nlm.nih.gov/pubmed/18806303

ALZAMEND NEURO

Alzamend leadership team

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

Kenneth S. Cragun
Chief Financial Officer
30+ Years SEC reporting, Nasdaq CFO, multi-industry experience, including Biotech and Healthcare

David Katzoff
SVP Operations
30+ Years multi-industry experience, including Healthcare and Technology

Henry Nisser
EVP, General Counsel and Corporate Secretary
20+ years experience, U.S. securities compliance, M&A, equity/debt financings and corporate governance

ALZAMEND NEURO

Alzamend board of directors

Milton "Todd" Ault, III
Founder/Executive Chairman of Alzamend
Chairman & CEO of DPW Holdings
27+ years Financial Industry experience,
seasoned Wall Street CEO & activist investor

Virginia Lazala
VP & Legal Head, Oncology Global HR at
Novartis Pharmaceuticals Corporation
33+ Years multi-industry experience,
Pharmaceutical and Banking

William B. Horne
Chief Financial Officer at DPW Holdings
25+ years Financial Industry experience, prior "Big 4" auditor & healthcare executive

Jeffrey Oram
Principal at Godby Realtors
27+ years multi-industry experience,
Investments, Real Estate and Technology

Philip E. Mansour
CEO at MTIX International
25+ years multi-industry experience,
seasoned executive, manager & coach

ALZAMEND NEURO

Alzamend scientific advisory board

Eric McDade, DO
Associate Director, DIAN Trials Unit & Clinical Trials Leadership, Washington University School of Medicine
Associate Professor of Neurology, Washington University School of Medicine
157+ Peer-Reviewed Journal Publications

Lynne Fahey McGrath
Regulatory Affairs and Product Development Consultant in Bio-pharmaceutical industry
30+ years experience, Biotech and Pharmaceuticals
MPH/PHD, Public Health from UMDNJ - Robert Wood Johnson Medical School

Thomas M. Wisniewski, MD
Director, NYU Langone's Pearl I. Barlow Center for Memory Evaluation and Treatment
300+ Peer-Reviewed Medical Journal Publications (19 U.S. Patents Issued)
Leads a Research Laboratory Continuously Funded by the National Institutes of Health for 20+ Years

ALZAMEND NEURO

Alzamend strategic partner TAMM Net (FDA regulatory advisors)

Art Spaulding
Founder and President
25+ years experience, including market research, reimbursement and regulatory

Eve Del Rio, MD, PhD.
Epidemiologist/Immunologist
30+ years experience, including pre-IND, INDs, pre-NDA, NDAs and BLAs

Donald Reitberg, Pharm.D.
Pharmacologist
30+ year experience, including FDA briefing packages for Phases I-IV

Gary W. Wolfe, PhD., DABT
Pharmacologist/Toxicologist
30+ years experience preparing drug development plans for FDA approval

Appendix B - Development Report

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

I. Date Development Plan Initiated and Time Period Covered by this Report.

II. Development Report (4-8 paragraphs).

A. Activities completed since last report including the object and parameters of the development, when initiated, when completed and the results.

B. Activities currently under investigation, i.e., ongoing activities including object and parameters of such activities, when initiated, and projected date of completion.

III. Future Development Activities (4-8 paragraphs).

A. Activities to be undertaken before next report including, but not limited to, the type and object of any studies conducted and their projected starting and completion dates.
B. Estimated total development time remaining before a product will be commercialized.

IV. Changes to Initial Development Plan (2-4 paragraphs).

A. Reasons for change.
B. Variables that may cause additional changes.

V. Items to be Provided if Applicable:

A. Information relating to Licensed Products or Licensed Processes that has become publicly available, e.g., published articles, competing products, patents, etc.
B. Development work being performed by third parties, other than Licensee, to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
C. Update of competitive information trends in industry, government compliance (if applicable) and market plan.
D. Information and copies of relevant materials evidencing the status of any patent applications or other protection relating to Licensed Products, or Licensed Processes or the Licensed Patents.

PLEASE SEND DEVELOPMENT REPORTS TO:

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

Initials _____

Appendix C - Licensor Royalty Report

Licensee: _____
Agreement No.: _____
Inventor: _____
Technology#: _____
Period Covered: From: ___/___/2___ Through: ___/___/2___
Prepared By: _____
Date: _____
Approved By: _____
Date: _____

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

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

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

Total Royalty: _____ Conversion Rate: _____ Royalty in U.S. Dollars: $ _____
The following royalty forecast is non-binding and for Licensor's internal planning purposes only:
Royalty Forecast Under This Agreement:
Next Quarter: _____ Q2: _____ Q3: _____ Q4: _____

Initials _____

Total Royalty: _____ Conversion Rate: _____ Royalty in U.S. Dollars: $ _____

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

Royalty Forecast Under This Agreement: Next Quarter: _____ Q2: _____ Q3: _____ Q4: _____

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

PLEASE SEND ROYALTY REPORTS TO:

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

Initials _____

Appendix D - Milestones

1. Licensee has already provided Licensor a complete business plan and detailed management team attached herein as Appendix A.

2. By 20 months from the Effective Date, Licensee will have $5,000,000 of available non-contingent, operating capital to proceed with the exploration and development of Licensed Product. Capital will be from a third party who may or may not be an investor in Licensee and unused capital will be on deposit in a financial institutional acceptable to both Licensor and Licensee.

3. Company will meet the following Regulatory Milestones:

Due Date	**Event**
Completed September 2019	Pre-IND Meeting
October 30, 2020	IND filing
12 months from IND filing	First dosing of a patient in a clinical trial
12 months from completion of the first dosing of a patient	Completion of first clinical trial
36 months from completion of the first Phase II Clinical Trial	First patient treated in a Phase III Clinical Trial
July 1, 2027	First Commercial Sale

STANDARD EXCLUSIVE LICENSE AGREEMENT
WITH SUBLICENSING TERMS

Agreement # LIC19051

This Agreement is made effective *nunc pro tunc* November 1, 2019, (the "Effective Date") by and between the University of South Florida Research Foundation, Inc. (hereinafter called " Licensor"), a nonstock, nonprofit Florida corporation, under Chapter 617 Florida Statutes, and a direct support organization of the University of South Florida ("University") pursuant to section 1004.28 Florida Statutes and Alzamend Neuro Inc. (hereinafter called "Licensee"), a small corporation organized and existing under the laws of Delaware;

WHEREAS, University is the owner of certain inventions described in the "Licensed Patents" defined below (University Reference # 12B100);

WHEREAS, Licensor is the exclusive licensee of the Licensed Patents, and Licensor is willing to grant a license to Licensee under the Licensed Patents and Licensee desires a license to the Licensed Patents;

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

Section 1 **Definitions**

1.1 "Affiliate" means: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the Licensee or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the Licensee or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of Licensee or (d) any entity in which any officer or employee is also an officer or employee of Licensee or any person who is an officer or employee of Licensee or (e) any other relationship as in fact, constitutes actual control.

1.2 "Development Plan" means the written report summarizing the development activities that are to be undertaken by the Licensee to bring Licensed Products and/or Licensed Processes to the market. The Development Plan is attached as Appendix A.

1.3 "Development Report" means a written account of Licensee's progress under the Development Plan having at least the information specified on Appendix B to this Agreement, and shall be sent to the address specified on Appendix B .

1.4 "Investigator" means Drs. Roland (Doug) Shytle, Michael Zaworotko, Adam Smith and Naga Duggirala, while employed by Licensor.

1.5 "First Commercial Sale" means the first commercial sale, lease or other transfer, practice or disposition of any Licensed Product or Licensed Process for value in any country by Licensee or by a Sublicensee to a third party that is not a Licensee Affiliate or a Sublicensee.

1.6 "Know-How" means unpatented technology and/or information that was developed by the Investigator, including without limitation methods, processes, techniques, compounds, cell lines, materials, sequences, drawings, indications, data, results of tests, or studies, plans, and expertise, whether patentable or not, which relates specifically to the Licensed Patents and existing on the date hereof, only to the extent wholly owned and controlled by Licensor, except that, Know-How shall not include the Licensed Patents.

1.7 “Licensed Field” means the field of LiProSal (lithium co-crystal) for the treatment of Psychiatric Diseases/Disorders.

1.8 “Licensed Patents” means all of the following Licensor intellectual property:

1.8.1 the patent(s)/patent application(s) identified on Schedule 1.8 hereto;

1.8.2 any and all United States and foreign patent applications claiming priority to any of the patent(s) and patent application(s) identified on Schedule 1 hereto (except that in the case of continuation-in-part application(s), only to the extent that the subject matter claimed in such continuation-in-part application(s) is supported under 35 U.S.C 112 in the patent(s)/patent application(s) identified on Schedule 1 hereto); and

1.8.3 any and all patents issuing from the patent applications identified in section 1.8.1 and 1.8.2, including, but not limited to, letters patents, patents of addition, reissues, re- examinations, extensions, restorations, and supplementary protection certificates;

all to the extent owned or controlled by Licensor.

1.9 “Licensed Product” and “Licensed Process” means:

1.9.1 In the case of a Licensed Product, any product or part thereof, on a country-by-country basis, that:
(a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which such product is made, used, imported or sold; or
(b) is manufactured by using a process that is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which any such process is used or in which any such product is used, imported, or sold; or
(c) incorporates, utilizes, or was developed utilizing, Know-How or that is manufactured using Know-How or using a process developed using Know-How.

1.9.2 In the case of a Licensed Process, any process, on a country-by-country basis, that:
(a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents in any country in which such process is practiced; or
(b) incorporates, utilizes, or was developed utilizing, Know-How.

1.10 “Licensed Territory” means worldwide.

1.11 “Net Sales” means the total dollar amount invoiced on sales of Licensed Product and/or Licensed Processes by Licensee, Sublicensee or Affiliates. Total amount invoiced may include only promotional discounts allowed in amounts customary in the trade.

1.12 “Patent Challenge” means a challenge to the validity, patentability, enforceability and/or non-infringement of any of the Licensed Patents or otherwise opposing any of the Licensed Patents.

1.13 "Sublicense" means, an agreement or series of related agreements to, directly or indirectly, sublicense, grant any other right with respect to, or agree not to assert, any right licensed to Licensee under this Agreement. An agreement that is described in this definition is a Sublicense whether or not it is called a "sublicense" and whether or not it is included in a stand-alone document or is part of series of agreements establishing a broader collaboration, development, asset purchase, joint venture agreement or other arrangement.

1.14 "Sublicensee" means any third party to whom Licensee grants a Sublicense.

Section 2 **Grant**

2.1 License.

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

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

2.2 Sublicense.

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

2.2.2 Licensee shall provide Licensor with an unredacted copy of each Sublicense agreement (and in the case of a series of related agreements, all such related agreements) and any subsequent amendments which transfers intellectual property rights granted hereunder, at least thirty (30) days prior to the execution of the Sublicense agreement. Licensee shall also provide Licensor with copies of any Sublicensee milestone and royalty reports.

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

Section 3 **Due Diligence**

3.1 Development.

3.1.1 Licensee agrees to and warrants that:

(a) it has, or will obtain, the expertise necessary to independently evaluate the inventions of the Licensed Patents and Know-How;

(b) it will actively and diligently pursue the Development Plan, (see Appendix A) to the end that the inventions of the Licensed Patents will be utilized to provide Licensed Products and/or Licensed Processes for sale in the retail market within the Licensed Field;

(c) it will diligently develop markets for Licensed Products and Licensed Processes;

(d) and, until the date of First Commercial Sale of Licensed Products or Licensed Processes, it will supply Licensor with a written Development Report annually within fifteen (15) days after the end of the calendar year (see Appendix B).

3.1.2 Licensee agrees that the First Commercial Sale of products to the retail customer shall occur on or before July 1, 2027 or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3 hereto. In addition, Licensee will meet the milestones shown in Appendix D or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3. Licensee will notify Licensor in writing as each milestone is met.

3.1.3 Upon written request by Licensee to negotiate extensions of any milestones or due dates set forth in Appendix D, such request to be received by Licensor no less than ninety (90) days prior to any of the due dates subject of such request, set forth in this Section 3.1.3, such request fully describing Licensee's diligent efforts to achieve the milestone required to be met by such due date, Licensor shall consider in good faith such requests. Upon granting such request, Licensor and Licensee shall negotiate such extensions in good faith.

3.1.4 University's policies may require approval of clinical trials involving technology invented by Licensor. Accordingly, Licensee will notify Licensor prior to commencing any clinical trials at the University's facility or any affiliated medical facilities.

3.1.5 Every year Licensor is required to report on statistics that are relevant to growth of businesses in Florida. On January 31 and July 31 of each year, Licensee shall provide to Licensor a report that includes: the current number of employees in Florida, the total number of employees, information about whether Licensee has gone public or been acquired, detail on the amount and sources of funding, any new products that have been introduced to the market, the number of employees who are University graduates, and the number of University interns for the period since the last report was received. This specific information will be held in confidence and provided in the aggregate. No information obtained under this Section 3.1.5 will be identified as being connected with Licensee absent agreement of the Licensee.

Section 4 **Payments**

4.1 License Issue Fee.

Licensee agrees to pay Licensor a License Issue Fee of ten thousand Dollars ($10,000.00) due on the first anniversary of the Effective Date.

4.2 Intentionally Omitted

4.3 Royalty.

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

(i) three percent (3%) for Net Sales of Licensed Products, for each product, on a country- by-country basis, as defined by Sections 1.7.1 (a), and 1.7.1(b); and

(ii) three percent (3%) for Net Sales of Licensed Processes, for each process, on a country-by-country basis, as defined by Section 1.7.2 (a); and

(iii) two percent (2%) for Net Sales of Licensed Products and Licensed Processes sold during a period of regulatory exclusivity as defined by the appropriate regulatory body for such Licensed Product or Licensed Process in the country in which such Licensed Product or Licensed Process is sold.

Royalties shall be payable until the later, on a country-by-country basis, of (i) the expiration of the last-to-expire Licensed Patents, (ii) the expiration of any applicable regulatory exclusivity period in such country, and (iii) ten (10) years from the First Commercial Sale of a Licensed Product or Licensed Process in such country in which the Licensed Product or Licensed Process is sold.

4.4 Other Payments.

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

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

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

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

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

Licensee is entering into multiple license agreements with Licensor related to USF Technology 12B100, also referred to as the LiProSal product. For the avoidance of doubt, it is understood and agreed that only one of each such milestone payments shall be payable as between LIC19050 and LIC19051 ..

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

4.5 Accounting for Payments.

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

4.5.2 Any amounts which remain unpaid after the date they are due toLicensor shall accrue interest from the due date at the rate of 1.5% per month. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. Licensee shall also be responsible for repayment to Licensor of any attorney, collection agency, or other out-of-pocket Licensor expenses required to collect overdue payments due under this Section 4 or any other applicable Section of this Agreement.

4.5.3 Except as otherwise directed, all amounts owing to Licensor under this Agreement shall be paid in U.S. dollars to Licensor at the following address:

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

4.5.4 A certified full accounting statement showing how any amounts payable to Licensor under Section 4 have been calculated shall be submitted to Licensor on the date of each such payment. In addition to being certified, such accounting statements shall contain a written representation signed by an executive officer of Licensee that states that the statements are true, accurate, and fairly represent all amounts payable to Licensor pursuant to this Agreement. For earned royalties, such accounting shall be on a per- country and product line, model or trade name basis and shall be summarized on the form shown in Appendix C – Licensor Royalty Report of this Agreement. For earned royalties, in the event no payment is owed to Licensor because the amount of minimum royalties paid has not been exceeded or otherwise, an accounting demonstrating that fact shall be supplied to Licensor.

4.5.5 Licensor is exempt from paying income taxes under U.S. law. Therefore, all payments due under this Agreement shall be made without deduction for taxes, assessments, or other charges of any kind which may be imposed on Licensor by any government outside of the United States or any political subdivision of such government with respect to any amounts payable to Licensor pursuant to this Agreement. All such taxes, assessments, or other charges shall be assumed by Licensee.

Section 5 **Certain Warranties and Disclaimers of Licensor**

5.1 Licensor warrants that, except as otherwise provided under Section 17.1 of this Agreement with respect to U.S. Government interests, it is the owner or exclusive licensee of the Licensed Patents or otherwise has the right to grant the licenses granted to Licensee in this Agreement. However, nothing in this Agreement shall be construed as:

(a) a warranty or representation by Licensor as to the validity or scope of any right included in the Licensed Patents;
(b) a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of third parties;
(c) an obligation to bring or prosecute actions or suits against third parties for infringement of Licensed Patents;
(d) an obligation to furnish any services other than those specified in this Agreement; or
(e) a warranty or representation by Licensor that it will not grant licenses to others to make, use or sell products not covered by the claims of the Licensed Patents which may be similar and/or compete with products made or sold by Licensee.

5.2 Licensee warrants that it has the power and authority to enter into and perform its obligations under this Agreement and that the execution of this Agreement by it has been duly and validly authorized by all necessary corporate action and its obligations under this Agreement are valid and binding and enforceable against it in accordance with their terms.

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

Section 6 **Record Keeping**

6.1 Licensee and its Sublicensee(s) shall keep books and records sufficient to verify the accuracy and completeness of Licensee's and its Sublicensee(s)'s accounting referred to above, including without limitation, inventory, purchase and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to the Licensed Products and/or Licensed Processes. Such books and records shall be preserved for a period not less than six years after they are created or as required by federal law, both during and after the term of this Agreement.

6.2 Licensee and its Sublicensee(s) shall take all steps necessary so that Licensor may, within thirty (30) days of its written request, audit, review and/or copy all of the books and records at a single U.S. location to verify the accuracy of Licensee's and its Sublicensee(s)'s accounting. Such review may be performed by any authorized employees of Licensor as well as by any attorneys and/or accountants designated by Licensor, upon reasonable notice and during regular business hours. If a deficiency with regard to any payment hereunder is determined, Licensee and its Sublicensee(s) shall pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4.5.1. If a royalty payment deficiency for a calendar year exceeds three percent (3%) of the royalties paid for that year, then Licensee and its Sublicensee(s) shall be responsible for paying Licensor's out-of-pocket expenses incurred with respect to such review.

6.3 At any time during the term of this Agreement, Licensor may request in writing that Licensee verify the calculation of any past payments owed to Licensor through the means of a self-audit. Within ninety (90) days of the request, Licensee shall complete a self-audit of its books and records to verify the accuracy and completeness of the payments owed. Within thirty (30) days of the completion of the self-audit, Licensee shall submit to Licensor a report detailing the findings of the self-audit and the manner in which it was conducted in order to verify the accuracy and completeness of the payments owed. If Licensee has determined through its self- audit that there is any payment deficiency, Licensee shall pay Licensor the deficiency along with applicable interest under Section 4.5.1 with the submission of the self-audit report to Licensor.

Section 7 **Patent Prosecution**

7.1 Licensor shall be solely responsible for preparing, filing, prosecuting and maintaining the Licensed Patents using counsel of its choice. Licensor shall provide Licensee with copies of all documents sent to and received from the United States Patent and Trademark Office and foreign patent offices relating to Licensed Patents. Licensee agrees to keep such information confidential. Licensor shall provide Licensee with a reasonable opportunity to comment on the preparation, prosecution and maintenance of the Licensed Patents and will consider Licensee's comments in good faith.

7.2 Intentionally Omitted

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

Section 8 **Infringement and Invalidity**

8.1 Licensee shall inform Licensor promptly in writing of any alleged infringement of the Licensed Patents by a third party and of any available evidence thereof.

8.2 During the term of this Agreement, Licensor shall have the right, but shall not be obligated, to prosecute at its own expense any such infringements of the Licensed Patents. If Licensor prosecutes any such infringement, Licensee agrees that Licensor may include Licensee as a co- plaintiff in any such suit, without expense to Licensee.

8.3 If within six (6) months after having been notified of any alleged infringement, Licensor shall have been unsuccessful in persuading the alleged infringer to desist and shall not have brought an infringement action against the alleged infringer, or if Licensor shall notify Licensee at any time prior thereto of its intention not to bring suit against the alleged infringer, then, and in those events only, Licensee shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents, and Licensee may, for such purposes, use the name of Licensor as party plaintiff. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Licensor, which consent shall not be unreasonably withheld. Licensee shall indemnify Licensor against any order for costs that may be made against Licensor in such proceedings.

8.4 In the event that a declaratory judgment action is brought against Licensor or Licensee by a third party alleging invalidity, unpatentability, unenforceability, or non-infringement of the Licensed Patents, Licensor, at its option, shall have the right within twenty (20) days after commencement of such action to take over the sole defense of the action at its own expense. If Licensor does not exercise this right, Licensee shall be responsible for the sole defense of the action at Licensee's sole expense, subject to Sections 8.5 and 8.6.

8.5 In the event that Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, Licensor shall have the right, but not the obligation, to voluntarily join such litigation, represented by its own counsel at its own expense. In the event that Licensor or Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by Licensor or Licensee for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of Licensor relating to the suit, and next toward reimbursement of any unreimbursed expenses and legal fees of Licensee relating to the suit. The balance remaining from any such recovery shall be divided equally between Licensee and Licensor.

8.6 In any suit in which either party is involved to enforce or defend the Licensed Patents pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

8.7 In the event Licensee, its Affiliate or Sublicensee brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor, unless and until Licensor terminates this Agreement pursuant to Section 9, Licensee shall continue to pay royalties and make other payments pursuant to this Agreement with respect to the contested Licensed Patent(s) as if such Patent Challenge were not underway until the contested Licensed Patent(s) is adjudicated invalid or unenforceable by a court of last resort. If at the end of such Patent Challenge any of the challenged Licensed Patents remain valid, then at Licensor's option, (i) all royalties and other payments due under this Agreement with respect to such Patent Rights will double or (ii) Licensor may terminate this Agreement if it has not already done so.

Section 9 **Term and Termination**

9.1 The term of this license shall begin on the Effective Date of this Agreement and continue until the later of the date that no Licensed Patent remains a pending application or an enforceable patent, or the date on which Licensee's obligation to pay royalties expires pursuant to Section 4.3 above.

9.2 Licensee may terminate this Agreement at any time by giving at least sixty (60) days written notice of such termination to Licensor. Such a notice shall be accompanied by a statement of the reasons for termination.

9.3 Licensor may terminate this Agreement if (a) Licensee (i) is delinquent on any report or payment; (ii) is not diligently developing and commercializing Licensed Products and Licensed Processes; (iii) misses a milestone described in Appendix D; (iv) is in breach of any provision; (v) provides any false report; (vi) goes into bankruptcy, liquidation or proposes having a receiver control any assets; (vii) violates any laws or regulations of applicable government entities; or (viii) shall cease to carry on its business pertaining to Licensed Patents; or (b) if payments of earned royalties under Section 4.3, once begun, cease for more than two (2) calendar quarters. Termination under this Section 9.3 will take effect 30 days after written notice by Licensor, unless Licensee remedies the problem in that 30-day period, except that termination under Section 9.3 (vi) will occur immediately and automatically upon the occurrence of the event and require no action by Licensor.

9.4 If Licensee or any of its Affiliates brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may immediately terminate this Agreement and/or the license granted hereunder. If a Sublicensee brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may send a written demand to Licensee to terminate such Sublicense. If Licensee fails to so terminate such Sublicense within forty-five (45) days after Licensor's demand, Licensor, at its option, may (i) elect to immediately terminate this Agreement and/or the license granted hereunder or (ii) to double all royalties and other payments due under this Agreement with respect to such Patent Rights.

9.5 If Licensee, any of its Affiliates or a Sublicensee (i) brings a Patent Challenge against Licensor or (ii) assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), and if Licensor does not choose to exercise its rights to terminate this Agreement pursuant to Section 9.4 then, in the event that such the Patent Challenge is successful, Licensee will have no right to recoup any consideration, including royalties, paid during the period of challenge. In the event that the Patent Challenge is unsuccessful, Licensee shall reimburse Licensor for all reasonable legal fees and expenses incurred in its defense against the Patent Challenge.

9.6 Licensor may immediately terminate this Agreement upon the occurrence of the second separate default by Licensee within any consecutive three-year period for failure to pay royalties, patent or any other expenses when due.

9.7 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Licensee shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination, and any minimum royalties shall be prorated as of the date of termination by the number of days elapsed in the applicable calendar year. Licensee may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that Licensee shall remain obligated to provide an accounting for and to pay running royalties thereon.

9.8 Licensee shall be obligated to deliver to Licensor, within ninety days of the date of termination of this agreement, complete and unredacted copies of all documentation prepared for or submitted for all regulatory approvals of Licensed Products or Licensed Processes.

Section 10 **Assignability**

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

Section 11 **Dispute Resolution Procedures**

11.1 Mandatory Procedures.

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

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

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

11.1.3 Not more than fifteen (15) days after the giving of such notice of issues, each party shall deliver to the other party a list of the names and addresses of at least three individuals, any one of whom would be acceptable as a neutral advisor in the dispute (the "Neutral Advisor") to the party delivering the list. Any individual proposed as a Neutral Advisor shall have experience in determining, mediating, evaluating, or trying intellectual property litigation and shall not be affiliated with the party that is proposing such individual.

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

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

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

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

11.2 Failure to Resolve Dispute.

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

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

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

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

Section 13 **Use of Names**

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

Section 14 **Miscellaneous**

14.1 This Agreement shall be construed in accordance with the internal laws of the State of Florida without regard to its conflicts of law principles.

14.2 The parties hereto are independent contractors and not joint venturers or partners.

14.3 Licensee shall ensure that it applies patent markings that meet all requirements of U.S. law, 35 U.S.C. §287, with respect to all Licensed Products subject to this Agreement.

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

14.5 Licensee shall not encumber or otherwise grant a security interest in any of the rights granted hereunder to any third party.

14.6 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Contract Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. Licensor neither represents that a license is or is not required or that, if required, it shall be issued.

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

14.8 Survival.

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

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

Section 15 **Notices**

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

15.1 All payments and royalty reports to: USF Research Foundation

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

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

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

15.2 If to Licensee:

Alzamend Neuro™, Inc.
3802 Spectrum Blvd., Suite 112C Tampa, FL 33612

Section 16 **Contract Formation and Authority**

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

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

16.2 Force Majeure.

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

Section 17 **United States Government Interests**

17.1 It is understood that the United States Government (through any of its agencies or otherwise) has funded research during the course of or under which any of the inventions of the Licensed Patents were conceived or made. The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §202-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the inventions of such Licensed Patents for governmental purposes. Any license granted to Licensee in this Agreement shall be subject to such right.

17.2 Licensee agrees that for Licensed Products covered by the Licensed Patents that are subject to the non-exclusive royalty-free license to the United States Government, said Licensed Products will be manufactured substantially in the United States. Licensee further agrees that it shall abide by all the requirements and limitations of U.S. Code, Title 35, Chapter 18, and implementing regulations thereof, for all patent applications and patents invented in whole or in part with federal money.

Section 18 **Confidentiality**

18.1 Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential and that is marked "confidential" by the disclosing party or that is confirmed in writing within ten (10) days after verbal disclosure (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, Sublicensees or agents. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section 18 shall extend for a period of five (5) years from termination or expiration of this Agreement.

Section 19 **University Rules and Regulations**

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

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

UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.

/s/ David Conrad Date: June 10, 2020
David Conrad, Director
Technology Transfer Office

ALZAMEND NEURO, INC.

/s/ Stephan Jackman Date: June 8, 2020
Stephan Jackman, CEO

ACKNOWLEDGED AND AGREED:

UNIVERSITY OF SOUTH FLORIDA BOARD OF TRUSTEES A PUBLIC BODY CORPORATE

/s/ Keith Anderson June 10, 2020
Keith Anderson, Director

INVENTOR

Dr. Roland (Doug) Shytle

SCHEDULE 1.8 – LICENSED PATENTS

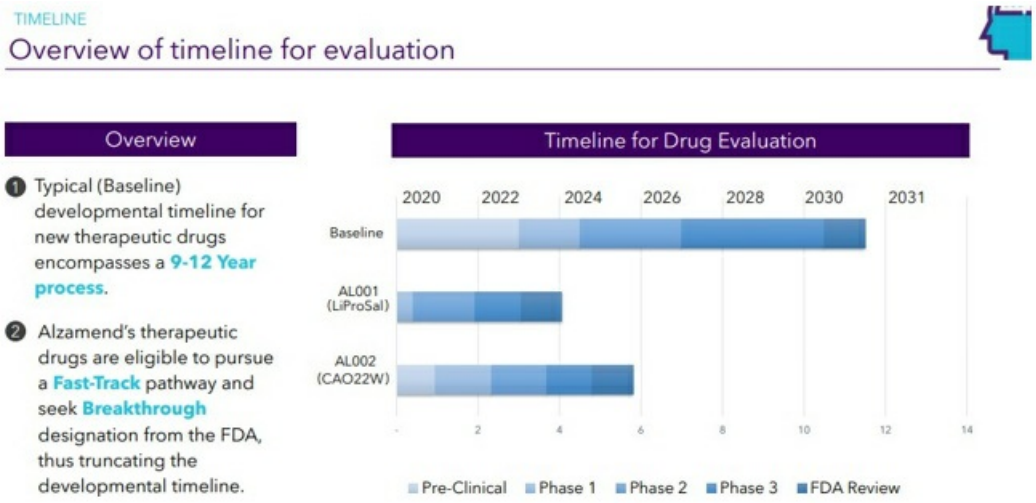
United States Patent No. 9,840,521, entitled “Organic Anion Lithium Ionic Cocrystal Compounds and Compositions”, filed 09/24/2015 and granted 12/12/2017.

Appendix A - Development Plan

I. Development Program

Development activities to be undertaken.

Continue with Reg A+ funding strategy already in place. See attached plan slide deck below that outlines fundraising and preclinical/clinical path:



COMPANY OVERVIEW

Overview of company goals and projects

Company history

Biotechnology company dedicated to:

- Researching, developing and commercializing **preventions**, **treatments and cures** for Alzheimer's
- Working on **two therapeutics** licensed from the **University of South Florida**, one of the top 20 institutions in the nation for patented research and their portfolio of proprietary solutions.

Current projects

AL001 (aka LiProSal): an ionic cocrystal of lithium that may greatly **reduce** or **eliminate** the **symptoms of agitation** and other endpoints for mild to moderate stage patients diagnosed with Alzheimer's.

AL002 (aka CAO22W): adjuvant-free therapeutic vaccine intended for use as a **treatment** or **prophylactic** for patients diagnosed with Alzheimer's.

GENERAL OVERVIEW

Overview of Alzheimer's disease

Key Statistics:

6th leading cause of death in the United States

Every 65 seconds someone in the United States develops Alzheimer's Disease

14 million people are projected to be living with Alzheimer's by 2050

1-in-10 Americans over the age of 65 are estimated to be afflicted with Alzheimer's

Alzheimer's Disease:

Alzheimer's disease is an irreversible, progressiv brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks. In most people with Alzheimer's, symptoms first appear in their early to mid-60's. Estimates vary, but experts suggest that more than 5.8 million Americans may have Alzheimer's, considered by many as "the most feared" disease.

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

GENERAL SCIENTIFIC OVERVIEW

Overview of our science

Therapeutic Drug	Synopsis	Strength	Status
AL001	• Use of patented Ionic Cocrystal (ICC) technology delivering a therapeutic combination of Lithium, Proline, and Salicylate • Lithium as a treatment of agitation and other possible symptoms in patients with indication of Alzheimer's disease • Other potential indications: Dementia, Parkinson's Disease, ALS, Depression, Bi-Polar Disorder, Mania, Post Traumatic Stress Disorder (PTSD), Suicidality, etc.	• Exclusive license for Cocrystal delivery system to treat Alzheimer's disease • Eligible for "breakthrough therapy" designation from FDA • Seeking a 505(b)(2) clinical trial pathway from FDA • Formulation may importantly expand the range of therapeutic categories amenable to lithium treatments, with enhanced safety • Has the potential of becoming the replacement for all lithium therapy on the market	• Filed Pre-IND in Q3 2019 • Filing IND in Q4 2020 • Commencing Phase 1 human clinical trials in Q4 2020
AL002	• 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. • Also seeks to mitigate adverse reactions from a patient's immunological system experienced during pre-clinical trials including the highly publicized Elan study (AN-1972)	• Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of AD • Difficult to manufacture and hence not easily replicated by competitors • Eligible for "breakthrough therapy" status via FDA • Antibody responses induced after one inoculation (Pre-Clinical) and lasted for 4 months • Inflammation cytokines like IL1 and TNF.alpha, which are considered being related to inflammation didn't increase with antibody level increase	• Completing pre-clinical studies Q2 2020 • Filing Pre-IND in Q3 2020 • Filing IND in Q4 2020 • Commencing Phase 1 human clinical trials in Q4 2020

ALZAMEND NEURO

Overview of AL001 (aka LiProSal or LISPRO)

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

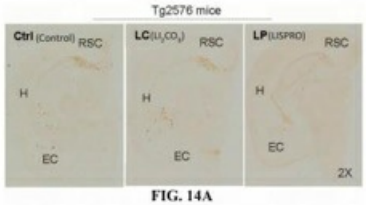


FIG. 14A

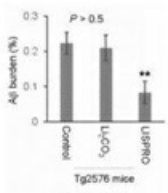


FIG. 14B

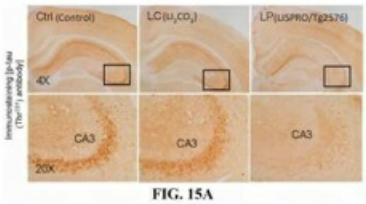


FIG. 15A

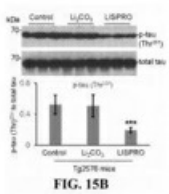
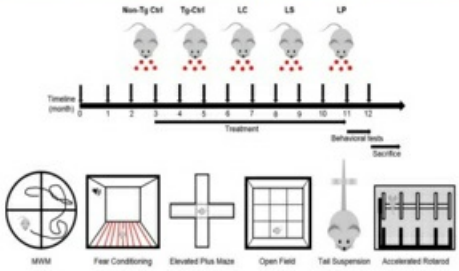


FIG. 15B

ALZAMEND NEURO

Overview of AL001 (aka LiProSal or LISPRO)



- With the goal of improving lithium's therapeutic profile, we investigated the safety, pharmacokinetics, and therapeutic efficacy of LiProSal™ (LP), compared with lithium carbonate (LC) and lithium salicylate (LS) across a host of preclinical models of AD.
- Female APPSWE/PS1dE9 mice at 4 months of age were orally treated with LP, LS, or LC for 9 months followed by determination of body weight, growth of internal organs, and cognitive and non-cognitive behavior.
- Untreated age-matched non-transgenic littermates served as wild-type (WT) controls.

The Results

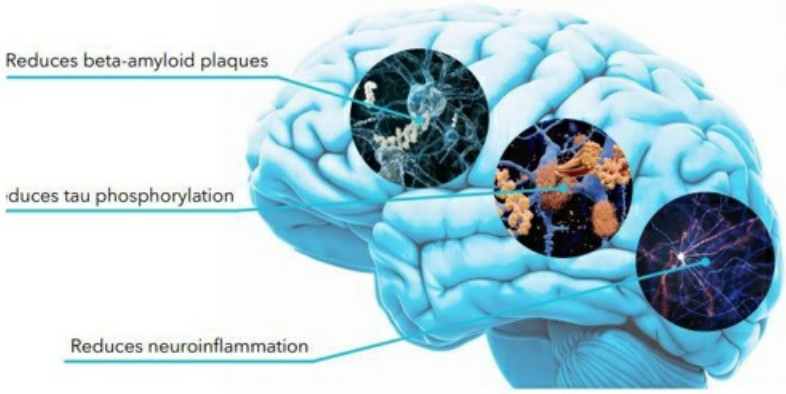
- No significant differences in body weight, brain, heart, lung, spleen, liver or kidney were found between lithium treated- and untreated APPSWE/PS1dE9 cohorts.
- LP treatment **improved cognitive function**, as shown by lower escape latency during training and probe trial of the Morris water maze (MWM) test and longer contextual freezing time during the fear conditioning test.
- LP treatment also **reduced depression**, as assessed by tail suspension test, and irritability, as assessed by touch escape test.
- LP treatment afforded s**uperior protection against cognitive impairment** as determined by contextual fear conditioning test and irritability in comparison with LC or LS treatment.
- Chronic LP treatment **prevent cognitive deficits**, depression and irritability in female APPSWE/PS1dE9 mice, and is superior in improving associative learning and memory and irritability compared with lithium salicylate or carbonate treatments, supporting the potential of this lithium formulation for the treatment of AD.

ALZAMEND NEURO

Potential Impact of AL001

Arrests cognitive decline

Slows the progression of Alzheimer's disease



Improves brain health:

- **Increases** BDNF or brain-derived neurotrophic factor promoting neurogenesis
- **Reduces** the production of inflammatory cytokines
- **Inhibits** glycogen synthase kinase-3 beta (GSK3β)
- **Increases** docosahexaenoic acid (DHA) – an omega-3 fatty acid essential for brain development
- **Inhibits** microglial activation
- **Promotes** neuronal stem cell differentiation
- **Promotes** autophagy, clearing damaged cells

BUDGET DETAILS

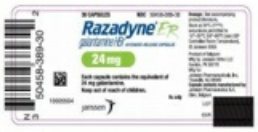
Overview of preliminary budgetary estimate

Category	2019	2020	2021	2022	2023	5-year Total
Phase 1 clinical trial*	$ -	$ 7,035,000	$ -	$ -	$ -	$ 7,035,000
Phase 2 clinical trial*	-	-	20,000,000	7,000,000	-	27,000,000
Phase 3 clinical trial*	-	-	30,000,000	40,000,000	40,000,000	110,000,000
License fees	280,000	400,000	2,425,000	1,000,000	-	4,105,000
Outsourced clinical services	767,000	706,000	475,000	570,000	684,000	3,202,000
SG&A expenses	963,000	3,200,000	2,655,000	2,826,000	3,014,000	12,658,000
Total	$ 2,010,000	$ 11,341,000	$ 55,555,000	$ 51,396,000	$ 43,698,000	$ 164,000,000

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

COMPETITIVE LANDSCAPE

Overview of Alzheimer's Disease drugs on the market



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

*Aricept - Eisai Co., Ltd. Third Quarter Financial Results (https://www.eisai.com/ir/library/settlement/pdf/e201BQ3_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).
*Thomson Reuters Report - (https://www.researchgate.net/publication/274930518_Spotlight_on_Alzheimers_disease_a_Thomson_Reuters_Pharma_Matters_report).

COMPETITIVE LANDSCAPE

Overview of AL001 commercial market evaluation

Potential annual revenue

Patient Population	Price per patient/yearly	10% Market Capture	20% Market Capture	30% Market Capture
16.2 Million - Depression	$2,400	$3.9 Billion	$7.8 Billion	$11.7 Billion
13.0 Million – PTSD	$4,100	$5.3 Billion	$10.6 Billion	$15.9 Billion
5.8 Million - Alzheimer	$3,000	$1.7 Billion	$3.5 Billion	$5.1 Billion
5.7 Million - Bipolar Disorder	$1,800	$1.0 Billion	$2.0 Billion	$3.0 Billion
Total 40.7 Million – Patient Population		$12 Billion	$24 Billion	$36 Billion

Medication cost per year for Depression: https://depression.informedchoices.ca/types-of-treatment/medication-treatment/cost-of-medication/
Medication cost per year for PTSD: https://www.marketwatch.com/story/what-ptsd-costs-families-2014-04-04
Medication cost per year for Alzheimer: https://www.takeda.com/siteassets/system/investors/report/quarterlyannouncements/fy2017/fy2017-full-year-results/qr2017_q4_d_en.pdf.
Medication cost per year for Bipolar Disorder: https://www.ncbi.nlm.nih.gov/pubmed/18806303

ALZAMEND NEURO

Alzamend leadership team

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

Kenneth S. Cragun
Chief Financial Officer
30+ Years SEC reporting, Nasdaq CFO, multi-industry experience, including Biotech and Healthcare

David Katzoff
SVP Operations
30+ Years multi-industry experience, including Healthcare and Technology

Henry Nisser
EVP, General Counsel and Corporate Secretary
20+ years experience, U.S. securities compliance, M&A, equity/debt financings and corporate governance

ALZAMEND NEURO

Alzamend board of directors

Milton "Todd" Ault, III
Founder/Executive Chairman of Alzamend
Chairman & CEO of DPW Holdings
27+ years Financial Industry experience,
seasoned Wall Street CEO & activist investor

Virginia Lazala
VP & Legal Head, Oncology Global HR at
Novartis Pharmaceuticals Corporation
33+ Years multi-industry experience,
Pharmaceutical and Banking

William B. Horne
Chief Financial Officer at DPW Holdings
25+ years Financial Industry experience, prior "Big 4" auditor & healthcare executive

Jeffrey Oram
Principal at Godby Realtors
27+ years multi-industry experience,
Investments, Real Estate and Technology

Philip E. Mansour
CEO at MTIX International
25+ years multi-industry experience,
seasoned executive, manager & coach

ALZAMEND NEURO

Alzamend scientific advisory board

Eric McDade, DO
Associate Director, DIAN Trials Unit & Clinical Trials Leadership, Washington University School of Medicine
Associate Professor of Neurology, Washington University School of Medicine
157+ Peer-Reviewed Journal Publications

Lynne Fahey McGrath
Regulatory Affairs and Product Development Consultant in Bio-pharmaceutical industry
30+ years experience, Biotech and Pharmaceuticals
MPH/PHD, Public Health from UMDNJ - Robert Wood Johnson Medical School

Thomas M. Wisniewski, MD
Director, NYU Langone's Pearl I. Barlow Center for Memory Evaluation and Treatment
300+ Peer-Reviewed Medical Journal Publications (19 U.S. Patents Issued)
Leads a Research Laboratory Continuously Funded by the National Institutes of Health for 20+ Years

ALZAMEND NEURO

Alzamend strategic partner TAMM Net (FDA regulatory advisors)

Art Spaulding
Founder and President
25+ years experience, including market research, reimbursement and regulatory

Eve Del Rio, MD, PhD.
Epidemiologist/Immunologist
30+ years experience, including pre-IND, INDs, pre-NDA, NDAs and BLAs

Donald Reitberg, Pharm.D.
Pharmacologist
30+ year experience, including FDA briefing packages for Phases I-IV

Gary W. Wolfe, PhD., DABT
Pharmacologist/Toxicologist
30+ years experience preparing drug development plans for FDA approval

Appendix B - Development Report

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

I. Date Development Plan Initiated and Time Period Covered by this Report.

II. Development Report (4-8 paragraphs).

A. Activities completed since last report including the object and parameters of the development, when initiated, when completed and the results.

B. Activities currently under investigation, i.e., ongoing activities including object and parameters of such activities, when initiated, and projected date of completion.

III. Future Development Activities (4-8 paragraphs).

A. Activities to be undertaken before next report including, but not limited to, the type and object of any studies conducted and their projected starting and completion dates.
B. Estimated total development time remaining before a product will be commercialized.

IV. Changes to Initial Development Plan (2-4 paragraphs).

A. Reasons for change.
B. Variables that may cause additional changes.

V. Items to be Provided if Applicable:

A. Information relating to Licensed Products or Licensed Processes that has become publicly available, e.g., published articles, competing products, patents, etc.
B. Development work being performed by third parties, other than Licensee, to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
C. Update of competitive information trends in industry, government compliance (if applicable) and market plan.
D. Information and copies of relevant materials evidencing the status of any patent applications or other protection relating to Licensed Products, or Licensed Processes or the Licensed Patents.

PLEASE SEND DEVELOPMENT REPORTS TO:

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

Initials _____

Appendix C - Licensor Royalty Report

Licensee: _____
Agreement No.: _____
Inventor: _____
Technology#: _____
Period Covered: From: ___/___/2___ Through: ___/___/2___
Prepared By: _____
Date: _____
Approved By: _____
Date: _____

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

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

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

Total Royalty: _____ Conversion Rate: _____ Royalty in U.S. Dollars: $ _____
The following royalty forecast is non-binding and for Licensor's internal planning purposes only:
Royalty Forecast Under This Agreement:
Next Quarter: _____ Q2: _____ Q3: _____ Q4: _____

Initials _____

Total Royalty: _____ Conversion Rate: _____ Royalty in U.S. Dollars: $ _____

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

Royalty Forecast Under This Agreement: Next Quarter: _____ Q2: _____ Q3: _____ Q4: _____

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

PLEASE SEND ROYALTY REPORTS TO:

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

Initials _____

Appendix D - Milestones

1. Licensee has already provided Licensor a complete business plan and detailed management team attached herein as Appendix A.

2. By 20 months from the Effective Date, Licensee will have $5,000,000 of available non-contingent, operating capital to proceed with the exploration and development of Licensed Product. Capital will be from a third party who may or may not be an investor in Licensee and unused capital will be on deposit in a financial institutional acceptable to both Licensor and Licensee.

3. Company will meet the following Regulatory Milestones:

Due Date	**Event**
Completed September 2019	Pre-IND Meeting
October 30, 2020	IND filing
12 months from IND filing	First dosing of a patient in a clinical trial
12 months from completion of the first dosing of a patient	Completion of first clinical trial
36 months from completion of the first Phase II Clinical Trial	First patient treated in a Phase III Clinical Trial
July 1, 2027	First Commercial Sale