

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Confidential Draft Submission No. 1
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

ALZAMEND NEURO, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

81-1822909

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

3802 Spectrum Boulevard, Suite 112C
Tampa, Florida 33612
Tel.: (844) 722-6333

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Stephan Jackman
Chief Executive Officer
Alzamend Neuro, Inc.
3802 Spectrum Boulevard, Suite 112C
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

It is requested that copies of notices and communications from the Securities and Exchange Commission be sent to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☐

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

	Proposed Maximum	
	Aggregate	
Title of Each Class of Securities to be Registered	Offering Price (1)	Amount of Registration Fee
Shares of common stock, par value \$0.0001 per share (2)(3)	\$ 50,000,000	\$ 5,455
Representative's common stock purchase warrants (4)	--	--
	\$ 3,125,000	\$ 340.94
Common stock underlying representative's common stock purchase warrants (2)(5)		
Total	\$ 53,125,000	\$ 5,795.94

- (1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.
- (2) Pursuant to Rule 416, there are also being registered such indeterminable additional securities as may be issued to prevent dilution as a result of stock splits, stock dividends or similar transactions.
- (3) Includes shares the underwriters have the option to purchase to cover over-allotments, if any.
- (4) In accordance with Rule 457(g) under the Securities Act, no separate registration fee is required with respect to the warrants registered hereby.
- (5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 125% of the public offering price. As estimated solely for the purpose of recalculating the registration fee pursuant to Rule 457(g) under the Securities Act, the proposed maximum aggregate offering price of the representative's warrants is equal to 125% of \$2,500,000 (5% of \$50,000,000).

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a) may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus

Subject to Completion dated December 29, 2020

_____ Shares



Common Stock

This is an initial public offering of shares of common stock of Alzamend Neuro, Inc.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be between \$ _____ and \$ _____ per share.

We have applied to list our common stock for trading on the NYSE American under the symbol ALZA.

We are an “emerging growth company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves risks. See the section titled “Risk Factors” beginning on page 12 to read about factors you should consider before buying shares of our common stock.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

- (1) See the section titled “Underwriting” for additional information regarding compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional _____ shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus to cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about _____, 2021.

The date of this prospectus is _____, 2021

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Through and including _____, 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses that we have prepared. Neither we nor the underwriters take any responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of the shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

For investors outside the United States: We and the underwriters have not done anything that would permit a public offering of the shares of our common stock or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Market, Industry and Other Data

This prospectus contains estimates, projections and other information concerning market, industry and other data. We obtained this data from our own internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which these data are derived. These data involve a number of assumptions and limitations, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed in the section of this prospectus titled "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. While we believe such information included in this prospectus is generally reliable, we have not independently verified any third-party information.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the sections of this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our," "us" and "our company" refer to Alzamend Neuro, Inc.

Our Company

We are an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders. With our two current and future product candidates, we aim to bring treatments or cures to market at a reasonable cost as quickly as possible. Far too many individuals – patients and caregivers – suffer from the burden created by these devastating diseases. Our primary target, Alzheimer's disease, was among the most-feared diseases (second only to cancer) among Americans, according to a 2011 survey by the Harvard School of Public Health. Alzheimer's is also the sixth leading cause of death in the United States according to a 2020 report from the Alzheimer's Association. To date, 5.8 million Americans suffer from Alzheimer's, which directly impacts more than 16 million Americans who provide an estimated 18.6 billion hours of unpaid care, valued at \$244 billion, according to data provided by the Alzheimer's Association. In 2020, the estimated healthcare costs for treating individuals with Alzheimer's in the United States was over \$305 billion, including \$206 billion in Medicare and Medicaid payments. These costs could rise as high as \$1.1 trillion by 2050 if no treatment or cure is found, the Alzheimer's Association reported.

Our Product Candidates

Our current pipeline consists of two novel therapeutic drug candidates:

- **AL001** – A patented ionic co-crystal technology delivering a therapeutic combination of lithium, proline and salicylate, known as AL001, through two royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc., as licensor, and
- **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 a patient's immunological system to combat Alzheimer's, known as AL002, through a royalty-bearing exclusive worldwide license from the same licensor.

Our lead candidate, AL001, is expected to provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's and other neurodegenerative diseases and psychiatric disorders. Based on nonclinical data, AL001 ionic 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 more than 35 years and human toxicology regarding lithium use has been well characterized, mitigating the potential regulatory burden for safety data. The results from one human cohort study published in the International Journal of Psychiatry and Neurosciences in January 2010 indicated that lithium had a preventive effect on the development of dementia in patients with bipolar disorder in comparison with anticonvulsants, antidepressants and antipsychotics. These findings suggest that lithium may

exert some of its long-term beneficial effects in the treatment of affective disorders via underappreciated neuroprotective effects.

The results of randomized, placebo-controlled clinical trials of lithium in the treatment of patients with Alzheimer's dementia and subjects with mild cognitive impairment have been widely published. Clinical studies have indicated that lithium administered at doses lower than those used for affective disorders can favorably impact Alzheimer's outcomes. A study appearing in the British Journal of Psychiatry in 2011 reported that lithium was superior to a placebo, evidencing a slower decline of cognitive function as measured by the Alzheimer's Disease Assessment Scale cognitive subscale. Given the absence of adequate treatments for this highly prevalent disease, the potential efficacy of lithium in the long-term management of Alzheimer's may positively impact public health. There is an unmet medical need for safe and effective Alzheimer's treatments, particularly for treatments with neuroprotective properties.

We submitted a Pre-Investigational New Drug (PIND) briefing package to the U.S. Food and Drug Administration (FDA) in July 2019 that argued against the need for any further preclinical safety studies. Pursuant to the FDA response letter, we believe the proposed test parameters for AL001 appear reasonable to support a Phase I study, thereby allowing us to conduct human clinical trials. Following Phase III clinical trials, we intend to seek approval to commercialize AL001 via a New Drug Application (NDA). We have been asked to provide a scientific bridge to a listed drug to support the adequacy of the nonclinical program. According to the FDA, the adequacy of the nonclinical data will be a matter for review. If the adequacy of the nonclinical data is not sufficient for the FDA, we will then be required to conduct a clinical pharmacokinetics animal study (an expected six week study) of AL001 to be considered for FDA approval. We received feedback from the FDA regarding the PIND briefing package and have begun the process of finalizing the Investigational New Drug (IND) application and, while FDA approval is not guaranteed, we expect to receive approval to begin a Phase I clinical trial with human subjects by March 31, 2021. While the FDA has not given us any indication as to whether AL001 will receive "breakthrough therapy" designation or be permitted to use the Section 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.

We believe that our ability to re-engineer lithium solid dosage forms in order to optimize performance has the potential to address a wide range of clinical applications ranging from neurodegenerative disorders, such as Alzheimer's, amyotrophic lateral sclerosis (known as ALS), Huntington disease, multiple sclerosis, Parkinson's disease and traumatic brain injury, to more psychiatric conditions such as bipolar disorder, depression, mania, post-traumatic stress disorder and suicidality. This novel approach is intended to achieve the desired therapeutic outcome of enhanced penetration through the blood-brain barrier and sustained brain lithium concentrations while systemic exposures (and toxicities) are mitigated for other organ systems. The optimal modified-release lithium dosing approach should avoid acutely toxic peak concentrations in blood, as well as in the brain, and should maintain such blood concentrations for a predictable, clinically relevant time, with overall low systemic exposures that mitigate the potential for adverse events. The lithium delivery system would ideally be adaptable to a dosing regimen that maintains therapeutic brain lithium concentrations consistently for the longest possible time while allowing only modest exposures and providing adequate recovery periods between doses for other organ systems.

We have an additional preclinical candidate for Alzheimer's indication, AL002, which has transitioned from early-stage development to an extensive program of preclinical study and evaluation with an anticipated completion date of March 31, 2021. We plan to file an IND application with the FDA with respect to AL002 in the second quarter of 2021 and prepare to conduct a Phase I clinical trial in the third quarter of 2021.

Our Development Pipeline

The following chart provides an overview of the current development stages of our therapeutic product candidates.

Therapeutic Drug	Synopsis	Strength	Status
AL001	<ul style="list-style-type: none"> Use of patented Ionic Co-crystal (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, Bipolar disorder, Mania, Post-traumatic stress disorder and Suicidality 	<ul style="list-style-type: none"> Exclusive license for Co-crystal delivery system for Alzheimer's and psychiatric indications Eligible for "breakthrough therapy" designation from FDA Seeking a Section 505(b)(2) clinical trial pathway from FDA Formulation may 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 	<ul style="list-style-type: none"> Filed Pre-IND in Q3 2019 Filing IND in Q1 2021 Commencing Phase I human clinical trials in Q1 2021
AL002	<ul style="list-style-type: none"> 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 preclinical trials including the highly publicized Elan study (AN-1972) 	<ul style="list-style-type: none"> Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of Alzheimer's Difficult to manufacture and hence not easily replicated by competitors Eligible for "breakthrough therapy" status via FDA Antibody responses induced after one inoculation (Preclinical) and lasted for four months Inflammation cytokines like IL1 and TNF.alpha, which are considered being related to inflammation did not increase with antibody level increase 	<ul style="list-style-type: none"> Completing preclinical studies Q1 2021 Filing IND in Q2 2021 Commencing Phase I human clinical trials in Q3 2021

Our Proprietary Technology

AL001 Drug Candidate

Our lead candidate, AL001, is expected to provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's and other neurodegenerative diseases and psychiatric disorders. Lithium salts have a long history of human consumption beginning in the 1800s. In psychiatry, they have been used to treat mania and as a prophylactic for depression since the mid-20th century. Today, lithium salts are used as a mood stabilizer for the treatment of bipolar disorder. Although the FDA has approved no medications as safe and effective treatments for suicidality, lithium has proven to be the only drug that consistently reduces suicidality in patients with neuropsychiatric disorders. Despite these effective medicinal uses, current FDA-approved lithium pharmaceuticals (lithium carbonate and lithium citrate) are limited by a narrow therapeutic window that requires regular blood monitoring of plasma lithium levels and blood chemistry by a clinician to mitigate adverse events. Because conventional lithium salts (carbonate and citrate) are eliminated relatively quickly, multiple administrations throughout the day are required to safely reach therapeutic plasma concentrations. 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.

Scientists from the University of South Florida have developed a new lithium co-crystal composition and method of preparation that allow for lower dosages to achieve therapeutic brain levels of lithium for psychiatric disorders, broadening lithium's therapeutic index. The compound offers improved physicochemical properties compared to existing forms of lithium, giving it the potential to be developed as an anti-suicidal drug or for use against mood disorders.

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. Results from recent clinical studies suggest that lithium treatment may reduce dementia development while preserving cognitive function and reducing biomarkers associated with Alzheimer's disease.

The team of inventors from the University of South Florida have specifically designed, synthesized and characterized the novel ionic co-crystal of lithium (AL001). AL001 has been shown to exhibit improved nonclinical pharmacokinetics compared to current FDA-approved lithium products, and 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. Our preclinical studies concluded the following:

- Low doses of AL001 are safe and effective in reducing Alzheimer's pathology;
- AL001 has no effect on renal COX2 activity, a biomarker of renal toxicity, while markedly reducing abnormal beta-amyloid pathology, tau phosphorylation and neuro-inflammation;
- AL001 treatment did not induce tissue pathological damage in the heart, kidneys, liver and lungs by a general autopsy. In contrast, equimolar doses of lithium carbonate enhanced renal COX2 expression while having little or no impact on Alzheimer's pathology;
- AL001, 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;
- No significant differences in body weight, brain, heart, lungs, spleen, liver or kidneys were found between cohorts treated with AL001 and untreated cohorts;
- AL001 treatment improved cognitive function, as shown by lower escape latency during training and probe trial of the Morris water maze test and longer contextual freezing time during the fear conditioning test;
- AL001 treatment reduced depression, as assessed by tail suspension test, and irritability, as assessed by touch escape test;
- AL001 treatment afforded superior protection against cognitive impairment as determined by contextual fear conditioning test and irritability in comparison with lithium carbonate treatment; and
- Chronic AL001 treatment prevents cognitive deficits, depression, and irritability, and is superior in improving associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer's disease.

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 required by an NDA. Those drugs that qualify for the Section 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 Section 505(b)(2) regulatory pathway, AL001 would be eligible for three to five 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 approximately four years.

AL002 Drug Candidate

The other patented solution that we have licensed to commercialize is 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. The proposed mechanism of action is through the pulsed-Dendritic Cell (DC) activation of T-cells that yields to immune-based clearance of brain amyloid. Preclinical studies support that infusion with AL002-pulsed DC in transgenic mice is associated with lower amyloid burden and improved neurobehavioral performance. This is likely to be mediated by an anti-inflammatory effect in addition to the immunogenicity of this therapy.

AL002 is based on the theory that Alzheimer's symptoms are caused by plaque deposits composed of protein fragments called beta-amyloid that build up between nerve cells. One hypothesis is that a special type of immune cell, natural beta-amyloid antibodies, may play a role in preventing plaque build-up in people without Alzheimer's. As people age, their immune system may degrade, and some people may be unable to produce natural beta-amyloid antibodies which leads to the plaque build-

up causing Alzheimer's disease.

AL002 is intended to elicit an immune response to product anti-amyloid antibodies, which can then neutralize circulated beta-amyloid and prevent additional plaque build-up. The mutant antigen within AL002 was selected specifically for its high HLA binding affinity avoiding the need for an adjuvant, which may cause adverse (Th1) immune response.

AL002 is an autologous modified DC treatment. AL002 is a patient-specific therapy where the patient will undergo leukapheresis, a nonsurgical treatment used to reduce the quantity of white blood cells in the bloodstream, to isolate peripheral blood monocytes that are subsequently matured into DCs using an IL4+ GM-CSF cocktail. The DCs are incubated with a modified amyloid beta (A β) peptide (AL002 peptide) to sensitize them, and then administered to the same patient. Multiple preclinical studies and more than ten years of research have been conducted in preparation for this application.

Significant evidence has accumulated recently suggesting that immunotherapy is a highly promising modality of treatment in Alzheimer's. Most current immune-based active investigations are focused on passive immunization by pre-prepared A β antibody administration. Active immunization may offer additional or more lasting effect on the clearance of amyloid and a safer approach due to its reliance on autologous immune mechanisms. Further, preliminary evidence suggests a recurrence of the amyloid accumulation after clearance with the immunoglobulins. A prior attempt at engaging the immune system to treat Alzheimer's was conducted using the immunization with pre-aggregated synthetic A β (AN-1792) combined with the immunogenic adjuvant QS-21. The Phase IIa study with AN-1792 was terminated by the FDA due to severe meningoencephalitis in ~6% of vaccinated subjects. This was thought to be caused by the use of a strong non-specific antigenic determinant T-cell epitope in the A β 1-42 peptide and the inclusion of a QS21 adjuvant and polysorbate-80 stabilizing agent in the vaccine formulation.

Modified cell therapies, especially dendritic cells, may provide a safer and more patient-specific active immunization. Ex-vivo modification of DC as a modality of treatment has been previously used in oncological therapeutics. It has been shown to be relatively safe and is able to engage the immune system to attack the target tissues with success. Its use in Alzheimer's therapeutics is relatively recent. We are proposing to conduct a first-in-human Phase I study of autologous DC-pulsed with a modified A β epitope. Preclinical work supports that it is associated with positive anti-inflammatory response and a decrease in brain amyloid contents.

We believe that AL002 is ideally positioned for a breakthrough therapy designation. If we successfully acquire a breakthrough therapy designation for new drug approvals, we believe we can receive FDA approval for AL002 in approximately four years.

AL001 and AL002 will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before either of them or any successors are likely to provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval for and commercialize AL001 or AL002, 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 these therapeutic drug candidates 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 these drug candidates, and we would be unable to continue our operations as currently planned.

Our Business Strategy

We intend to develop and commercialize therapeutics with the potential to significantly improve the lives of individuals afflicted by Alzheimer's and other neurodegenerative diseases and psychiatric disorders. To achieve these goals, we are pursuing the following key business strategies:

- **Advance clinical development of AL001 and AL002 for Alzheimer's treatment.** For our lead candidate, AL001, we have submitted a PIND briefing package to the FDA with proposed testing parameters and have begun the process to finalize an IND application. We intend to commence Phase I human clinical trials for AL001 in the first quarter of 2021. Our preclinical candidate, AL002, is in early stages of development. We intend to complete preclinical study and evaluation of AL002 in the first quarter of 2021 and commence Phase I human clinical trials in the third quarter of 2021.
- **Expand the development of AL001 and AL002 to include additional indications and delivery methods.** In addition to treating Alzheimer's, AL001 and AL002 have the potential to treat a wide range of neurodegenerative disorders. Other potential indications for AL001 include ALS, Huntington disease, multiple sclerosis, Parkinson's disease, bipolar disorder, depression, mania, post-traumatic stress disorder and suicidality. For AL002, we seek to mitigate adverse reactions experienced by patients' immunological systems in response to AL002 restoring immunological systems to combat Alzheimer's.
- **Focus on translational and functional endpoints to efficiently develop product candidates** We believe AL001 is ideally positioned for a Section 505(b)(2) regulatory pathway for new drug approvals, which would grant us three to five years of market exclusivity. We also believe AL001 and AL002 are ideally positioned for breakthrough therapy designations, making them eligible to receive FDA approval in approximately four years.
- **Optimize the value of AL001 and AL002 in major markets.** We intend to commercialize AL001 and AL002 by seeking marketing approval for both product candidates and partnering with biopharmaceutical companies seeking to strategically fortify pipelines and funding costly later-stage clinical development. 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.

Our Management Team and Advisors

Our leadership team includes experienced biotech and Fortune 500 executives who have both developed and commercialized drugs. Stephan Jackman, our Chief Executive Officer, brings more than 20 years of multi-industry experience and has been essential in creating our innovative translational development strategy. Kenneth S. Cragun, our Chief Financial Officer, brings over 30 years of multi-industry experience, including SEC reporting and serving as the chief financial officer of a publicly traded company listed on Nasdaq. Henry C.W. Nisser, our Executive Vice President and General Counsel, brings more than 20 years of experience in U.S. securities compliance, mergers and acquisitions, equity and debt financings and corporate governance. David Katzoff, our Chief Operating Officer, brings more than 30 years of multi-industry experience, including finance, human resources and operations.

Our scientific advisory board currently consists of Dr. Thomas M. Wisniewski and Dr. Eric McDade, leading researchers in the neurodegenerative and neuropathology fields. Dr. Wisniewski is a board-certified neurologist and neuropathologist and is the Director of the New York University Pearl Barlow Center for Memory Evaluation and Treatment, which operates an active research laboratory focusing on neurodegenerative disorders with a particular focus on the mechanisms that drive amyloid deposition in Alzheimer's and prion diseases. This work has led to more than 300 peer-reviewed publications, 25 issued patents and continuous funding from the National Institutes of Health (NIH) for over 26 years. Dr. McDade is a board-certified cognitive neurologist who has focused his activities on the evaluation of individuals with dementia syndromes and on developing a clinical research program that focuses on using brain imaging and cerebrospinal fluid markers to identify those at risk for Alzheimer's. Dr. McDade is the Associate Director of the Dominantly Inherited Alzheimer Trials Unit (DIAN-TU). The DIAN-TU is a global network of families at risk for a genetic form of Alzheimer's and is pioneering prevention trials for this young-onset form of the disease.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company. These risks are described more fully in the section titled “Risk Factors” in this prospectus. These risks include, but are not limited to, the following:

- We have a limited operating history;
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future;
- Even if this offering is successful, we will require substantial additional funding to finance our operations and complete the development and commercialization of AL001 and AL002. If we are unable to raise this funding when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations;
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our key business strategies;
- Our development of AL001 and AL002 may never lead to a marketable product;
- Our approach to targeting beta-amyloid plaque via AL002 is based on a novel therapeutic approach, which exposes us to unforeseen risks;
- We have concentrated our research and development efforts on the treatment of Alzheimer’s and other neurodegenerative diseases and psychiatric disorders, fields that have seen limited success in product development. Further, our product candidates are based on new approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and the regulatory approval process;
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and clinical trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all;
- The outbreak of the novel coronavirus disease, Covid-19, could adversely impact our business, including delaying our nonclinical studies and clinical trials;
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted;
- We plan to rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates; and
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Implications of Being an Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As such, we may take advantage of reduced disclosure and other requirements otherwise generally applicable to public companies, including:

- presentation of only two years of audited financial statements and related financial disclosure;
- exemption from requirement to have our registered independent public accounting firm attest to management’s assessment of our internal control over financial reporting;
- reduced disclosure about our executive compensation arrangements; and
- exemption from requirement to hold non-binding advisory votes on executive compensation or golden parachute arrangements.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least \$1.07 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies unless it otherwise irrevocably elects not to avail itself of this exemption. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we are no longer an emerging growth company or affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In addition, we are also a “smaller reporting company” because the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million as of October 31, 2020 and our annual revenue was less than \$100 million during the fiscal year ended April 30, 2020. We may continue to be a smaller reporting company after this offering in any given year if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of October 31 in the most recently completed fiscal year or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million as of October 31 in the most recently completed fiscal year. If we are a smaller reporting

company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Corporate Information

We were incorporated on February 26, 2016 as Alzamend Neuro, Inc. under the laws of the State of Delaware. Our executive offices are located at 3802 Spectrum Blvd., Suite 112C, Tampa, Florida 33612 and our telephone number is (844) 722-6333. We maintain a corporate website at www.alzamend.com.

Channels for Disclosure of Information

Investors and others should note that we use social media to communicate with the public about our company, our product candidates, new product developments and other matters. Any information that we consider to be material to an evaluation of our company will be included in filings on the SEC website, <http://www.sec.gov>, and may also be disseminated using our investor relations website, which can be found at <http://www.alzamend.com>, and press releases. However, we encourage investors, the media and others interested in our company to also review our social media channels.

We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website a part of this prospectus.

Trademarks and Service Marks

We use Alzamend, Alzamend Neuro, the Alzamend logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

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The Offering

Common stock offered by us	_____ shares
Common stock to be outstanding after this offering	_____ shares (or _____ shares if the underwriters exercise their option to purchase additional shares in full)
Underwriters' option to purchase additional shares of common stock from us	_____ shares
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$_____, or \$_____ if the underwriters exercise in full their option to purchase additional shares of common stock, assuming an initial public offering price of \$_____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discount and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering to make substantial expenditures to fund proprietary research and development of our AL001 and AL002 therapeutic drug candidates and to support preclinical testing and clinical trials necessary for regulatory filings. The remainder of the net proceeds will be used for working capital and other general corporate purposes.</p> <p>For a more complete description of our intended use of the proceeds from this offering, see the section of this prospectus titled "Use of Proceeds."</p>
Ownership after this offering	Milton C. (Todd) Ault III, our Executive Chairman, and our other directors and executive officers will beneficially own __% of our outstanding common stock after the completion of this offering.
Risk factors	Investing in our common stock involves a high degree of risk. See the section of this prospectus titled "Risk Factors" beginning on page __ and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Proposed NYSE American trading symbol	ALZA

The number of shares of our common stock to be outstanding after this offering is based on 79,762,858 shares of our common stock (including 15,000,000 shares of our common stock to be issued upon the conversion of our series A convertible preferred stock effective upon the closing of this offering) outstanding as of December 29, 2020, and excludes the following:

- outstanding warrants to purchase an aggregate of 6,775,136 shares of common stock at a weighted average exercise price of \$2.82 per share;
- outstanding stock options to purchase an aggregate of 23,800,000 shares of common stock at a weighted average exercise price of \$0.84 per share;
- convertible debt instruments to receive up to an aggregate of 245,999 shares of common stock at a weighted average conversion price of \$1.50 per share;
- _____ shares of common stock reserved for future grants pursuant to the exercise of options or other equity awards under our incentive compensation

_____ shares of common stock issuable upon the exercise of warrants we expect to grant to the underwriters in this offering.

Unless otherwise indicated, this prospectus assumes no exercise by the underwriters of their option to purchase up to an additional _____ shares of our common stock from us to cover over-allotments.

On June 28, 2018, we implemented a 1-for-4 reverse stock split of our outstanding shares of common stock. All share information contained in this prospectus reflects the 1-for-4 reverse stock split of our outstanding shares of common stock.

Summary Financial Data

The following tables set forth a summary of our financial data. The summary statements of operations data for the fiscal years ended April 30, 2019 and 2020 are derived from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the six months ended October 31, 2019 and 2020 and the summary balance sheet data as of October 31, 2020 are derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. You should read this summary data together with our financial statements and related notes included elsewhere in this prospectus and the information in the section of this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of our future results, and the results of operations for the six months ended October 31, 2020 are not necessarily indicative of the results to be expected for the full year ending April 30, 2021, or any other period. The summary financial data in this section are not intended to replace the financial statements and related notes included elsewhere in this prospectus.

	Year Ended April 30,		Six Months Ended October 31,	
	2019	2020	2019	2020
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 3,700,083	\$ 1,069,418	\$ 399,916	\$ 783,759
General and administrative	1,308,800	3,354,743	1,491,825	1,832,494
Total operating expenses	5,008,883	4,424,161	1,891,741	2,616,253
Loss from operations	(5,008,883)	(4,424,161)	(1,891,741)	(2,616,253)
Total other income (expense), net	146,387	13,925	8,893	(54,596)
Net loss	\$ (4,862,496)	\$ (4,410,236)	\$ (1,882,848)	\$ (2,670,849)
Basic and diluted net loss per common share	\$ (0.08)	\$ (0.06)	\$ (0.03)	\$ (0.04)
Basic and diluted weighted average common shares outstanding	58,843,040	71,253,580	70,913,449	72,262,858
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)		\$		\$
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)				

(1) See Notes 15 and 16 to our audited financial statements and Notes 12 and 13 to our unaudited interim condensed financial statements included in this prospectus for the calculation of our basic and diluted net loss per share attributable to common stockholders and our basic and diluted pro forma net loss per share attributable to common stockholders, and the weighted average number of shares used in computing the per share amounts.

	As of October 31, 2020		
	Actual	Pro Forma (1) (unaudited)	Pro Forma, As Adjusted (2) (unaudited)
Balance Sheet Data:			
Cash and cash equivalents	\$ 5,860		
Working capital(3)	\$ (666,767)		
Total assets	\$ 981,927		
Total liabilities	\$ 1,648,694		
Convertible preferred stock	\$ 75		
Accumulated deficit	\$ 14,456,718		
Total stockholders’ (deficit) equity	\$ (666,767)		

- (1) The pro forma balance sheet data in the table above gives effect to the conversion of our series A convertible preferred stock into 15,000,000 shares of our common stock effective upon the closing of this offering.
- (2) The pro forma, as adjusted balance sheet data in the table above gives effect to the pro forma adjustments described in footnote (1) above and the sale by us of _____ shares of our common stock in this offering at an assumed initial public offering price of \$_____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discount and estimated offering expenses payable by us. A \$1.00 increase (decrease) in the assumed initial public offering price of \$_____ per share would increase (decrease) the pro forma, as adjusted amount of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity (deficit) by approximately \$_____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discount and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of cash, cash equivalents and marketable securities, working capital, total assets and stockholders' equity (deficit) by approximately \$_____, assuming the assumed initial public offering price of \$_____ per share remains the same, and after deducting the estimated underwriting discount and estimated offering expenses payable by us. The pro forma, as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.
- (3) We define working capital as current assets less current liabilities. See our financial statements for further details regarding our current assets and current liabilities.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Company, Stage of Development and Financial Condition

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 October 31, 2020, we had cash of \$5,860 and an accumulated deficit of \$14,456,718. Since our inception, we have incurred recurring losses and for the six months ended October 31, 2020 and the year ended April 30, 2020, we incurred net losses of \$2,670,849 and \$4,410,236, respectively. 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 have a limited operating history on which to judge our business prospects and management.

We were incorporated in February 2016 and commenced operations shortly thereafter. We have a 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 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 scientific advisory board. 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.

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We will need but may be unable to obtain funding following this offering on satisfactory terms, which could dilute our stockholders and investors, 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 our 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 and there can be no assurance that Spartan Capital 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.

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 intellectual property from the University of South Florida Research Foundation.

There are certain initial license fees and milestone payments required to be paid by us to the University of South Florida Research Foundation, Inc., as licensor, pursuant to the terms of license agreements we have entered into with the licensor. The license agreement requires us to pay royalty payments of 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 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 our common stock. As an additional licensing fee for the license of the AL001 technologies, the licensor received 2,227,925 shares of our common stock equal to 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 our common stock until we have received a total of \$5,000,000 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 respective 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-AD License:

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

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AL002 License:

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

We have met the Pre-IND meeting milestone payment encompassing AL001. If we fail to meet a milestone payment 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 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 will be increased upon such issuance. The amount of the increase will be determined by multiplying the number of shares then owned by the licensor by a fraction; the numerator of which will be equal to the number of shares of our common stock outstanding immediately after the issuance of additional shares of our common stock, and the denominator of which will be equal to the sum of (i) the number of shares of our common stock outstanding immediately prior to the issuance of additional shares of our common stock plus (ii) the number of shares of our common stock which the aggregate consideration for the total number of additional shares of our common stock so issued would purchase at the Investment Price.

On June 10, 2020, we obtained two additional royalty-bearing exclusive worldwide licenses from the licensor to a therapy known as LiProSalTM. One of the additional licenses is for the treatment of neurodegenerative diseases excluding Alzheimer's disease and the other license is for the treatment of psychiatric diseases and disorders. LiProSalTM is an ionic cocrystal of lithium. There are certain license fees and milestone payments required to be paid for the licensing of the LiProSalTM technology, pursuant to the terms of the Standard Exclusive License Agreements with Sublicensing Terms, both dated June 10, 2020 and effective *nunc pro tunc* November 1, 2019, with the licensor and the University of South Florida (the "LiProSalTM License Agreements"). In addition, under each of the LiProSalTM License Agreements, a royalty payment of 3% is

required on net sales of products developed from the licensed technology. For the two additional LiProSalTM licenses, in the aggregate, we are required to pay initial license fees of \$20,000 no later than November 1, 2020. Additionally, under each of the LiProSalTM License Agreements, we are required to pay milestone payments on the due dates to the 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

These license agreements have an indefinite term that continue until the later of the date no licensed patent under the applicable agreement remains a pending application or enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, or the date on which the licensee's obligations to pay royalties expire under the applicable license agreement.

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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 a license agreement 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 a 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 plan 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 United States, Europe and elsewhere;

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- 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 AL001 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.

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.

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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 United States, 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 Drug Candidates

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:
 - o we may not be able to generate sufficient revenue or obtain financing to continue our operations;
 - o our ability to execute our current business plan will be materially impaired;
 - o our reputation in the industry and in the investment community would likely be significantly damaged; and
 - o the price of the common stock 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 United States, European Union 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 preclinical 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 United States, 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 United States 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 United States, 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:

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- 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 United States 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 United States 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.

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Our ability to market AL001, AL002 and any future product candidates in the United States, 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 United States 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 United States 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 United States 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 United States 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 United States, 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.

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Many states in the United States 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 United States 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 S. Cragun, our Chief Financial Officer, Henry C.W. Nisser, our Executive Vice President and General Counsel, and David Katzoff, our Chief Operating Officer, our as well as on our consultant, Dr. Chuanhai Cao, the neuroscientist who developed AL002, and Dr. Roland (Doug) Shytle, one of the inventors of AL001. 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.

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 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.

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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.

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.

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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.

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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.

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Risks Relating to Legal Matters

We received a subpoena from the Securities and Exchange Commission in the investigation known as “In the Matter of DPW Holdings, Inc.,” the consequences of which are unknown.

We received a subpoena from the Securities and Exchange Commission (SEC) that stated that the staff of the SEC is conducting an investigation 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 SEC 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 SEC or its staff that any violations of the federal securities laws have occurred. We have produced documents in response to the subpoena. The SEC may in the future require us to produce additional documents or information, or seek testimony from other members of our management team.

We are unaware of the scope or timing of the SEC’s investigation. As a result, we do not know how the SEC’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 SEC 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 SEC 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 SEC. Three members of our Board of Directors, Messrs. Ault, Horne and Nisser, are directors of DPW Holdings, Inc. There can be no assurance that any final resolution of this and any similar matters will not have a material adverse effect on our business, financial condition or results of operations.

We are subject to various claims and legal actions arising in the ordinary course of our business.

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.

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Further, 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.

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 Affiliates’ Control and Relationships

Insiders currently have, and will continue after this offering to have, substantial influence over us after this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.

In the aggregate, beneficial ownership of the shares of our common stock by management and affiliated parties represents approximately 53.3% of the outstanding shares of our common stock. After this offering, our directors, executive officers, holders of more than 5% of our outstanding common stock and their respective affiliates will beneficially own shares representing approximately ___% of our outstanding common stock, or ___% of our common stock if the underwriters exercise their option to purchase additional shares in full. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Members of the Board of Directors and executive officers of our company, DPW Holdings, Inc. and Avalanche International Corp. contain some of the same individuals, and may present potential conflicts of interest.

Our company is controlled by Milton C. (Todd) Ault III, our Executive Chairman, directly and through his controlling equity interest in Ault Life Sciences, Inc. and Ault Life Sciences Fund, LLC. Mr. Ault is also the Chairman, Chief Executive Officer and single largest stockholder (through Ault & Company, Inc.) of DPW Holdings, Inc., a publicly-traded diversified holding company focused primarily on the defense/aerospace, industrial and telecommunications industries (“DPW”). The Board of Directors and executive officers of our company and the board of directors and executive officers of DPW contain some of the same individuals, all of whom devote a portion of their business and professional time and efforts to the respective businesses of our company, DPW and/or Avalanche. William B. Horne, a director of our company, is the President and a director of DPW, Henry C.W. Nisser, our Executive Vice President, General Counsel and a director of our company, holds the same positions in DPW, and Kenneth S. Cragun, our Chief Financial Officer is the Chief Financial Officer of DPW. Additionally, Mr. Ault is the Chairman of Avalanche International Corp. dba MTIX International, a smaller publicly-traded company currently engaged in developing advanced materials and processing technology for textile applications (“Avalanche”). Mr. Horne is a director of Avalanche and its Chief Financial Officer, Mr. Nisser is its Executive Vice President and General Counsel, and Philip E. Mansour, a director of our company, is Avalanche’s President, Chief Executive Officer and a director.

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While we believe that our business and technologies are distinguishable from those of DPW and Avalanche, and that we do not compete in the markets in which DPW and Avalanche compete, Mr. Ault and the other named directors may have potential conflicts of interest with respect to, among other things, potential corporate opportunities, business combinations, joint ventures and/or other business opportunities that may become available to them, our company, DPW and/or Avalanche. Moreover, while Mr. Ault and the other named directors have agreed to devote a portion of their business and professional time and efforts to our company, potential conflicts of interest also include the amount of time and effort devoted by each of them to the affairs of DPW and Avalanche. We may be materially adversely affected if Mr. Ault and/or the other named directors choose to place the interests of DPW and/or Avalanche before those of our company. Each of Mr. Ault and the other named directors has agreed that, to the extent such opportunities arise, he will carefully consider a number of factors, including whether such opportunities were presented to him in his capacity as an officer or director of our company, whether such opportunities are within our company’s line of business or consistent with our strategic objectives and whether our company will be able to undertake or

benefit from such opportunities. In addition, our Board of Directors has adopted a policy whereby any future transactions between us and any of our subsidiaries, affiliates, officers, directors, principal stockholders or any affiliates of the foregoing will be on terms no less favorable to our company than could reasonably be obtained in “arm’s length” transactions with independent third parties, and any such transactions will also be approved by a majority of our disinterested outside directors. Mr. Ault and the other named directors owe fiduciary duties of care and loyalty to our company under Delaware law. However, the failure of our management to resolve any conflicts of interest in favor of our company could materially adversely affect our business, financial condition and results of operations.

Certain provisions of our certificate of incorporation allow concentration of voting power, 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. 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 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.

Risks Relating to Our Accounting Systems and Controls

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the regulations of the NYSE American, the rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending the year after this offering is completed, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to this offering, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

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We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by NYSE American, the SEC or other regulatory authorities.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

As a public company, we will be subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the requirements of SOX Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

Risks Relating to this Offering and Ownership of Our Common Stock

As a new investor, you will experience substantial dilution as a result of this offering

The public offering price per share will be substantially higher than the net tangible book value per share prior to the offering. Consequently, if you purchase our shares of common stock in this offering at a public offering price of \$_____ per share, you will incur immediate dilution of \$_____ per share. See “Dilution” for further information regarding the dilution resulting from this offering. This dilution is due in large part to the fact that our earlier investors, including our current holder of series A convertible preferred stock, paid substantially less than the initial public offering price when it acquired its shares. In addition, if the underwriters exercise their over-allotment option, you will experience further dilution.

There is no established trading market for our shares of common stock.

This offering constitutes our initial public offering of our shares of common stock, and no public market for our shares of common stock currently exists. We have applied to list our shares of common stock on the NYSE American LLC under the symbol “ALZA,” and if approved we expect the shares to be listed on the NYSE American, subject to completion of customary procedures. Any delay in the commencement of trading of the shares on the NYSE American would impair the liquidity of the market for the shares and make it more difficult for holders to sell the shares.

Even if our shares of common stock are listed on NYSE American, there can be no assurance that an active trading market for the shares will develop or be sustained after this offering is completed. The initial offering price has been determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial offering price were our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the financial ratios, market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. However, there can be no assurance that following this offering the shares will trade at a price equal to or greater than the offering price.

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In addition, the market price of the shares may be volatile. Many factors may have a material adverse effect on the market price of the shares, including, but not limited to:

- announcements of the failure to obtain regulatory approvals or receipt of a “complete response letter” from the FDA;
- announcements of restricted label indications or patient populations, or changes or delays in regulatory review processes;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- the failure of our testing and clinical trials;
- the impact of the ongoing COVID-19 pandemic on our business;
- product liability claims, other litigation or public concern about the safety of our product candidates or future products;
- any adverse changes to our relationship with licensors, manufacturers or suppliers;
- the loss of any of our key scientific or management personnel;
- any major changes in our Board of Directors or management;
- the failure to retain our existing, or obtain new, commercial partners;
- announcements concerning our competitors or the pharmaceutical industry in general;
- the failure to achieve expected product sales and profitability;
- the failure to obtain reimbursements for our product candidates as part of any pet healthcare insurance plan, or price reductions;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our cash position or operating results;
- manufacturing and supply issues related to our current or future product candidates for our development programs and commercialization;
- changes in financial estimates or recommendations by securities analysts;
- the termination of any of our existing license agreements;
- announcements relating to future licensing or development agreements;
- potential acquisitions;
- the trading volume of shares on NYSE American;
- sales of our shares by us, our executive officers or directors or our shareholders;
- fluctuations in the U.S. equity markets;
- changes in accounting principles;
- market conditions in the animal health sectors; and
- general economic conditions in the U.S. and elsewhere.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, upon the expiration of the market standoff and lock-up agreements, the early release of these agreements or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After this offering and after giving effect to the conversion of all outstanding shares of our series A convertible preferred stock and the exercise of outstanding warrants into an aggregate of _____ shares of our common stock, _____ shares of our common stock will be outstanding, or _____ shares of common stock if the underwriters exercise their option to purchase additional shares in full, based on our shares outstanding as of the date of this prospectus. Of these shares, the _____ shares we are selling in this offering, or _____ shares if the underwriters exercise their option to purchase additional shares in full, may be resold in the public market immediately. The remaining _____ shares, or _____% of our outstanding shares after this offering, or _____% of our outstanding shares after this offering if the underwriters exercise their option to purchase additional shares in full, are currently prohibited or otherwise restricted under securities laws, market standoff agreements entered into by our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters; however, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, these shares will be able to be sold in the public market beginning 180 days after the date of this prospectus. The representatives may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Shares issued upon the exercise of stock options outstanding under our stock incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. See the section of this prospectus titled “Shares Eligible for Future Sale” for additional information.

Moreover, upon completion of this offering, the holders of approximately _____ shares of our common stock will be eligible to exercise certain rights, subject to various conditions and limitations, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also plan to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section of this prospectus titled “Underwriting.” If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

We may fail to meet our publicly announced guidance or other expectations about our business, which would cause our stock price to decline.

We expect to provide guidance regarding our expected financial and business performance, such as projections regarding sales and product development, as well as anticipated future revenues, gross margins, profitability and cash flows. Correctly identifying key factors affecting business conditions and predicting future events is inherently an uncertain process and our guidance may not be accurate. Our guidance is based on certain assumptions such as those relating to anticipated FDA approval for our product candidates, the results of our clinical trials, the marketing of any of our product candidates, among many other factors. If our guidance is not accurate or varies from actual results due to our inability to meet our assumptions or the impact on our financial performance that could occur as a result of various risks and uncertainties, the market value of our common stock could decline significantly.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE American, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our Board of Directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our charter provides for 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 have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. We will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus titled "Use of Proceeds." We may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. Any failure by us to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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Our bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws that will become effective immediately prior to the closing of this offering provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our bylaws that will become effective immediately prior to the closing of this offering further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Because we do not intend to pay dividends on our common stock, you must rely on stock appreciation for any return on your investment.

We presently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. As a result, you must rely on stock appreciation and a liquid trading market for any return on your investment. If an active and liquid trading market does not develop, you may be unable to sell your shares of common stock at or above the initial public offering price or at the time you would like to sell.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus.

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.

Information regarding market and industry statistics contained in this prospectus 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.

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USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ _____ (or \$ _____ if the underwriters exercise their option to purchase additional shares in full), assuming an initial offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discount and offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, establish a public market for our common stock in order to facilitate future access to the public equity markets by us, our employees and our stockholders, obtain additional capital to support our operations and increase our visibility in the marketplace. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to continue to make substantial expenditures to fund proprietary research and development of our AL001 and AL002 therapeutic drug candidates and to support preclinical testing and clinical trials necessary for regulatory filings. The amount and timing of expenditures for these purposes will vary depending upon a number of factors, none of which can be predicted with certainty, such as the results of our research and development efforts, the timing, number, scope and success of our nonclinical studies and clinical trials, participation of strategic partners, changing competitive conditions, technological advances, patent considerations and the timing and success of any regulatory submissions.

A portion of the net proceeds of this offering may be used for the acquisition or licensing of complementary technologies, products or businesses. We currently have no commitments or understandings to make any such acquisitions or enter into any new licenses.

The net proceeds of this offering will also be available for working capital and other general corporate purposes, including enhancing our corporate infrastructure and systems to assist in creating a more robust means of tracking data, automating back office functions and improving our financial reporting system. We may allocate funds from other sources to fund some or all of these activities.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

Based upon our current operating plan, we estimate that our existing cash and cash equivalents and the anticipated net proceeds from this offering will be sufficient to fund our operating expenses and capital expenditure requirements at least through _____ 2022. In particular, we expect that the net proceeds from this offering will fund us through receipt of topline data readouts for our planned Phase I trial of AI001, as well as IND-enabling studies, IND application and Phase I trial of AI002 for the treatment of mild to moderate AD. However, the expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval and commercialization, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors. For additional information regarding our potential capital requirements, including factors that could cause actual costs to vary from the estimates set forth above, see the section of this prospectus titled "Risk Factors."

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share would increase or decrease, as applicable, the net proceeds to us from this offering by \$ _____, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1,000,000 shares in the number of shares offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by \$ _____, assuming that the assumed initial public offering price remains the same and after deducting the underwriting discount and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time when we need to seek additional capital.

As of the date of this prospectus, we intend to invest the net proceeds in short-term interest-bearing investment-grade securities, certificates of deposit or government securities. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our Board of Directors subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by any future debt instruments or preferred securities.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of October 31, 2020, as follows:

- on an actual basis;
- on a pro forma basis to reflect the conversion of all outstanding shares of our series A convertible preferred stock into 15,000,000 shares of common stock effective upon the closing of this offering, as if such conversion had occurred on October 31, 2020; and
- on a pro forma, as adjusted basis to further reflect our issuance and sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our consolidated financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” that are included elsewhere in this prospectus.

	As of October 31, 2020		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted(1) (unaudited)
Cash	\$ 5,860	\$ 90,285	\$ -
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 October 31, 2020 and April 30, 2020, respectively	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 October 31, 2020 and April 30, 2020, respectively	6,476	6,476	-
Additional paid-in capital	28,666,695	28,666,670	-
Note receivable for common stock – related party	(14,883,295)	(14,883,295)	-
Accumulated deficit	(14,456,718)	(14,456,718)	-
Total stockholders’ equity (deficit)	(666,767)	(666,767)	-
Total capitalization	\$ (666,767)	\$ (666,767)	\$ -

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma, as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$____, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) our pro forma, as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$____, assuming the assumed initial public offering price of \$____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma, as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of our common stock to be outstanding after this offering is based on 79,762,858 shares of our common stock (including 15,000,000 shares of our common stock issuable upon the conversion of our series A convertible preferred stock effective upon the closing of this offering) outstanding as of October 31, 2020, and excludes the following:

- outstanding warrants to purchase an aggregate of 6,775,136 shares of common stock at a weighted average exercise price of \$2.82 per share;
- outstanding stock options to purchase an aggregate of 23,800,000 shares of common stock at a weighted average exercise price of \$0.84 per share;
- convertible debt instruments to receive up to an aggregate of 245,999 shares of common stock at a weighted average conversion price of \$1.50 per share;
- _____ shares of common stock reserved for future grants pursuant to the exercise of options or other equity awards under our incentive compensation plans; and
- _____ shares of common stock issuable upon the exercise of warrants we expect to grant to the underwriters in this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma, as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of October 31, 2020 was \$(____), or \$(____) per share of our common stock. Our historical net tangible book

value (deficit) is the amount of our total tangible assets less our total liabilities and series a convertible preferred stock, which is not included within our stockholders' equity (deficit). Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of October 31, 2020.

Our pro forma net tangible book value as of October 31, 2020 was \$_____, or \$_____ per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the conversion of all outstanding shares of our series A convertible preferred stock into 15,000,000 shares of common stock effective upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of October 31, 2020, after giving effect to the conversion of all outstanding shares of our series A convertible preferred stock into an aggregate of October 31, 2020 shares of our common stock upon the completion of this offering.

After giving further effect to our sale of _____ shares of common stock in this offering at the assumed initial public offering price of \$_____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma, as adjusted net tangible book value as of October 31, 2020, would have been approximately \$_____, or approximately \$_____ per share. This represents an immediate increase in pro forma, as adjusted net tangible book value per share of \$_____ to our existing stockholders and an immediate dilution in pro forma, as adjusted net tangible book value per share of approximately \$_____ to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting pro forma, as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Historical net tangible book value per share as of October 31, 2020	
Pro forma increase in net tangible book value per share as of October 31, 2020	\$ -
Pro forma net tangible book value per share as of October 31, 2020	\$ -
Increase in pro forma, as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	\$ -
Pro forma, as adjusted net tangible book value per share after this offering	
Dilution per share to new investors purchasing shares in this offering	\$

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$_____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma, as adjusted net tangible book value per share after this offering by \$_____ per share and the dilution to new investors purchasing common stock in this offering by \$_____ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us would increase the pro forma, as adjusted net tangible book value per share after this offering by \$_____ and decrease the dilution per share to new investors participating in this offering by \$_____, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us would decrease the pro forma, as adjusted net tangible book value per share after this offering by \$_____ and increase the dilution per share to new investors participating in this offering by \$_____, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase _____ additional shares of common stock in this offering in full at the assumed initial public offering price of \$_____ per share, which is the midpoint of the estimated offering price range set forth on the cover of this prospectus, and assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma, as adjusted net tangible book value per share after this offering would be \$_____ per share, and the dilution in pro forma, as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be \$_____ per share.

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The following table summarizes, on a pro forma, as adjusted basis, as of October 31, 2020, the number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid, or to be paid, and the weighted-average price per share paid, or to be paid, by existing stockholders and by new investors in this offering at the assumed initial public offering price of \$_____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Number	Shares Purchased Percent	Total Consideration Amount	Weighted-Average Price Per Share
Existing stockholders		%	\$	%
New public investors				
Total		100%	\$	100%

The table above assumes no exercise of the underwriters' option to purchase _____ additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to _____% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to _____% of the total number of shares outstanding after this offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$_____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$_____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the total consideration paid by new investors by \$_____, assuming no change in the assumed initial public offering price.

The number of shares of our common stock to be outstanding after this offering is based on 79,762,858 shares of our common stock (including 15,000,000 shares of our common stock issuable upon the automatic conversion of our series A convertible preferred stock immediately prior to the closing of this offering) outstanding as of October 31, 2020, and excludes the following:

- outstanding warrants to purchase an aggregate of 6,775,136 shares of common stock at a weighted average exercise price of \$2.82 per share;
- outstanding stock options to purchase an aggregate of 23,800,000 shares of common stock at a weighted average exercise price of \$0.84 per share;
- convertible debt instruments to receive up to an aggregate of 245,999 shares of common stock at a weighted average conversion price of \$1.50 per share;

_____ shares of common stock reserved for future grants pursuant to the exercise of options or other equity awards under our incentive compensation plans; and

_____ shares of common stock issuable upon the exercise of warrants we expect to grant to the underwriters in this offering.

To the extent that any outstanding stock options are exercised or new stock options are issued under our incentive compensation plans, or we issue additional shares of common stock or convertible securities in the future, there will be further dilution to investors participating in this offering.

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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 prospectus. 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" and "Cautionary Statement regarding Forward-Looking Statements," and elsewhere in this prospectus.

Overview

We were incorporated 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. 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.

Going Concern

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 at October 31, 2020 is not sufficient to meet our anticipated cash requirements during the twelve-month period subsequent to the issuance of the most recent financial statements included in this prospectus. We believe 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 drug candidates. We may also be required to (a) seek collaborators for our drug candidates 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 our drug candidates that we would otherwise seek to deploy or commercialize. These matters raise substantial doubt about our ability to continue as a going concern. The financial statements contained in this prospectus do not include any adjustments that might become necessary should we be unable to continue as a going concern.

Critical Accounting Policies and Estimates

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 our company.

We have 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.

Our Plan of Operations

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 I clinical trial with human subjects in the first quarter 2021.

In November 2018, we began a toxicological preclinical study for AL002 with Charles River Laboratories, Inc. in compliance with FDA requirements. Upon completion of this toxicological study, anticipated to occur by the end of 2020, we expect to begin the process of finalizing the IND application process and move quickly forward to begin a Phase I clinical trial with human subjects during the latter half of 2021.

In November 2018, we adopted a Charter for our Scientific Advisory Board and have appointed two 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 Scientific Advisory Board members have clinical specializations, including extensive experience with Alzheimer's and other neurological diseases. We intend to rely on this advisory group of experts to help guide our therapies through the related scientific and manufacturing initiatives.

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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.

Results of Operations

Six Months Ended October 31, 2020 Compared to Six Months Ended October 31, 2019

The following table summarizes the results of our operations for the six months ended October 31, 2020 and 2019.

ALZAMEND NEURO, INC.
Statements of Operations (Unaudited)

	For the Six Months Ended October 31,	
	2020	2019
OPERATING EXPENSES		
Research and development	\$ 783,759	\$ 399,916
General and administrative	1,832,494	1,491,825
Total operating expenses	2,616,253	1,891,741
Loss from operations	(2,616,253)	(1,891,741)
OTHER INCOME (EXPENSE), NET		
Interest expense	(50,815)	-
Interest expense - related party	(5,487)	-
Interest income - related party	1,706	8,893
Total other income (expense), net	(54,596)	8,893
NET LOSS	\$ (2,670,849)	\$ (1,882,848)
Basic and diluted net loss per common share	\$ (0.04)	\$ (0.03)
Basic and diluted weighted average common shares outstanding	72,262,858	70,913,449

Revenue

We were 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 six months ended October 31, 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 six months ending October 31, 2020 and 2019, were \$1,832,494 and \$1,491,271, respectively. As reflected in the table below, general and administrative expenses primarily consisted of the following expense categories: management services, professional fees, stock compensation expense, salaries and benefits. The remaining general and administrative expenses of \$147,129 and \$69,396, respectively, primarily consisted of payments for advertising and promotion, transfer agent fees, travel, and other office expenses, none of which is significant individually.

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	For the Six Months Ended October 31,	
	2020	2019
Stock compensation expense	\$ 1,116,744	\$ 940,510
Professional fees	343,643	293,222
Salary and benefits	224,978	188,697
Other general and administrative expenses	147,129	69,396
Total general and administrative expenses	\$ 1,832,494	\$ 1,491,825

Stock compensation expense

During the six months ended October 31, 2020 and 2019, we incurred general and administrative stock compensation expense of \$1,116,744 and \$940,510, 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 six months ended October 31, 2020 and 2019, we reported professional fees of \$343,643 and \$293,222, respectively, which are principally comprised of the following items:

Six Months Ended October 31, 2020

- In June 2017, we entered into a five year consulting agreement with Spartan Capital Securities, LLC ("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 the prior private placement, we paid to Spartan a consulting fee of \$1,400,000 for the services to be rendered over the 60-month term of this consulting agreement. During the six months ended October 31, 2020, we recorded an expense of \$140,000 as a result of this consulting agreement.
- In June 2019, we entered into an uplisting agreement with Spartan pursuant to which Spartan has agreed to provide consulting services with respect to an IPO, merger, acquisition or sale of stock or assets, joint venture, strategic alliance or other similar transaction. We paid to Spartan a consulting fee of \$475,000 for the services to be rendered over the 24-month term of the uplisting agreement. During the six months ended October 31, 2020, we recorded an expense of \$118,750 as a result of this consulting agreement.
- During the six months ended October 31, 2020, we incurred \$25,132 in legal fees.
- During the six months ended October 31, 2020, we incurred \$61,420 in audit fees.

- During the six months ended October 31, 2019, we recorded an expense of \$140,000 as a result of the June 2017 Spartan consulting agreement discussed above.
- During the six months ended October 31, 2019, we recorded an expense of \$93,968 as a result of the June 2019 Spartan uplisting agreement discussed above.
- During the six months ended October 31, 2019, we incurred \$52,070 in legal fees.
- During the six months ended October 31, 2019, we incurred \$47,396 in audit fees.

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Salaries and Benefits

During the six months ended October 31, 2020 and 2019, we incurred \$224,978 and \$188,697, respectively, in employee-related expenses. As of October 31, 2020, we had one full-time and three part-time employees. We appointed Stephan Jackman as Chief Executive Officer as of November 30, 2018, Kenneth S. Cragun as Chief Financial Officer on December 15, 2018 and Henry Nisser as General Counsel and Executive Vice President on May 1, 2019.

Research and development expenses

Research and development expenses for the six months ending October 31, 2020 and 2019, were \$783,759 and \$399,916, respectively. As reflected in the table below, research and development expenses primarily consisted of professional fees, as well as licenses and fees.

	For the Six Months Ended October 31,	
	2020	2019
Professional fees	\$ 710,133	\$ 234,043
Licenses and fees	30,000	50,000
Stock compensation expense	43,626	115,873
Total research and development expenses	<u>\$ 783,759</u>	<u>\$ 399,916</u>

Licenses and fees

There are certain initial license fees and milestone payments required to be paid to the University of South Florida and the USF Research Foundation, for the licenses of the technologies, pursuant to the terms of the License Agreement with Sublicensing Terms (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 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 of 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 six months ended October 31, 2020, we incurred \$30,000 in license fees related to achieving the milestone of conducting pre-IND discussions with the FDA regarding AL001 under the new license agreements entered into on June 10, 2020 for the treatment of neurodegenerative diseases excluding Alzheimer's Disease and for the treatment of psychiatric diseases/disorders.

During the six months ended October 31, 2019, we incurred \$50,000 in license fees related to achieving the milestone of conducting pre-IND discussions with the FDA regarding AL001.

Professional fees

During the six months ended October 31, 2020 and 2019, we reported professional fees of \$710,133 and \$234,043, respectively, which are principally comprised of professional fees attributed to various types of scientific services, including FDA consulting services.

Stock compensation expense

During the six months ended October 31, 2020 and 2019, we incurred \$43,626 and \$115,873, respectively, in research and development stock compensation expense related to stock option grants to executives, employees and consultants. 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. 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.

Other income (expense), net*Interest expense*

Interest expense was \$50,815 for the six months ended October 31, 2020 related to the convertible promissory note issued in August 2020 including non-cash interest expense of \$45,625 recorded from the amortization of debt discount.

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Interest expense – related party

Interest expense – related party was \$5,487 for the six months ended October 31, 2020 related to the convertible promissory note – related party issued in August 2020 including non-cash interest expense of \$4,819 recorded from the amortization of debt discount.

Interest income – related party

During the six months ended October 31, 2020 and 2019, we reported interest income, related party of \$1,706 and \$8,893, respectively, relating to a promissory note from Avalanche.

Current and deferred income taxes

As of October 31, 2020 and 2019, we had deferred tax assets totaling \$3,302,943 and \$2,194,303, respectively. 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. As a result of the full valuation allowance, we did not record an income tax benefit during the six months ended October 31, 2020 and 2019.

Year Ended April 30, 2020 Compared to Year Ended April 30, 2019

The following table sets forth the results of our operations for the year ended April 30, 2020 compared to our results of operations for the year ended April 30, 2019.

	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

Revenues

We were incorporated 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 disease. 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 six months ended October 31, 2020 or the years ended April 30, 2020 and 2019, and we do not anticipate that we will generate revenues for the foreseeable future.

General and administrative expenses

General and administrative expenses for the years ended 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 \$120,347 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 individually significant.

	For the Year Ended April 30,	
	2020	2019
Stock compensation expense	\$ 2,054,294	\$ 396,170
Professional fees	752,795	545,771
Salary and benefits	427,306	96,460
Management services	—	160,000
Other general and administrative expenses	120,347	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 \$2,054,294 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 \$752,795 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 Capital 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 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 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 \$75,903 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.

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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 Stephan Jackman as full-time Chief Executive Officer as of November 30, 2018. On December 15, 2018, we retained our current Chief Financial Officer, Kenneth S. Cragun. On May 1, 2019, we hired Henry C.W. Nisser to be our Executive Vice President and General Counsel. On November 1, 2019, we hired David Katzoff to be our Senior Vice President of Operations and promoted him to Chief Operating Officer on December 18, 2020.

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 Chief Executive Officer, Philip E. Mansour, effective on November 18, 2018, and appointed Mr. Stephan Jackman as Chief Executive Officer 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 our activities. On December 15, 2018, we accepted the resignation of our former Chief Financial Officer, William B. Horne and retained our current Chief Financial Officer, 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 a Master Services Agreement entered into with Avalanche International Corp., 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 our company 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 Master Services Agreement expired as of December 31, 2018.

Research and development expenses

Research and development expenses for the years ended 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.

	2020	2019
Licenses and fees	\$ 50,487	\$ 2,489,600
Professional fees	859,432	1,142,887
Stock compensation expense	159,499	-
Other research and development expenses	-	67,596
Total research and development expenses	<u>\$ 1,069,418</u>	<u>\$ 3,700,083</u>

Licenses and fees

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

The license agreement for 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 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 our common stock. As an additional licensing fee for the license of the AL001 technologies, the licensor received 2,227,923 shares of our 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.

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During the year ended April 30, 2019, we incurred \$2,227,923 in non-cash charges from issuances of our 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 \$859,432 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 financial statements have been prepared on the basis that our company will continue as a going concern. As of October 31, 2020, we had cash of \$5,860 and an accumulated deficit of \$14,456,718. We have incurred recurring losses and reported losses for the six months ended October 31, 2020 totaling \$2,670,849. In the past, we have financed our operations principally through issuances of promissory notes and equity securities.

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 October 31, 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 prospectus. 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 products. We may also be required to (a) seek collaborators for our product candidates 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 our product candidates that we would otherwise seek to deploy or commercialize. These matters raise substantial doubt about our company's 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.

Recent Financing Transactions

In December 2020, we entered into a securities purchase agreement with an institutional investor to sell a convertible promissory note of our company in the principal amount of \$44,000 for a purchase price of \$40,000 and issue a five-year warrant to purchase 14,667 shares of our common stock. The convertible promissory note bears interest at 8% per annum, which principal and all accrued and unpaid interest are due six months after the date of issuance. The principal and interest earned on the convertible promissory note may be converted into shares of our common stock at \$1.50 per share. The exercise price of the warrant is \$3.00 per share.

In December 2020, DPW Holdings, Inc., a related party, provided \$1,000,000 in short-term advances to us.

In August 2020, we entered into a securities purchase agreement with an institutional investor to sell a convertible promissory note of our company in the principal amount of \$275,000 for a purchase price of \$250,000 and issue a five-year warrant to purchase 91,667 shares of our common stock. The convertible promissory note bears interest at 8% per annum, which principal and all accrued and unpaid interest are due six months after the date of issuance. The principal and interest earned on the convertible promissory note may be converted into shares of our common stock at \$1.50 per share. The exercise price of the warrant is \$3.00 per share.

In August 2020, we entered into a securities purchase agreement with DPW Holdings, Inc., a related party, to sell a convertible promissory note of our company in the principal amount of \$50,000 and issue a five-year warrant to purchase 16,667 shares of our common stock. The convertible promissory note bears interest at 8% per annum, which principal and all accrued and unpaid interest are due six months after the date of issuance. The principal and interest earned on the convertible promissory note may be converted into shares of our common stock at \$1.50 per share. The exercise price of the warrant is \$3.00 per share.

In April 2019, we entered into a securities purchase agreement with Ault Life Sciences Fund, LLC, a related party, for the sale of 10,000,000 shares of our common stock for a total purchase price of \$15,000,000, or \$1.50 per share, with 5,000,000 warrants with a five-year term and an exercise price of \$3.00 per share, and vesting upon issuance. The purchase price of \$15,000,000 was in the form of a note receivable initially with a 12-month term. The term of the note receivable was extended to December 31, 2021. While this transaction did not provide immediate liquidity to us, we expect future payments to be a source of our capital resources. During the six months ended October 31, 2020, proceeds from the note receivable for common stock, related party, were \$99,905.

On April 10, 2018, Avalanche International Corp. ("Avalanche"), a related party, issued a promissory note (the "AVLP Note") to evidence our loan of up to \$995,500 for a period ended on April 30, 2019, subject to the terms and conditions stated in the AVLP Note. The AVLP Note accrued interest at 10% per annum and included a 10% original issue discount. During the year ended April 30, 2019, \$105,000 was repaid. The balance outstanding on the AVLP Note as of October 31, 2019 was \$100,915. In August 2020, the principal and accrued interest on the AVLP Note was paid in full.

Impact of Coronavirus on Our Operations

In March 2020, the World Health Organization declared the outbreak of Covid-19 as a pandemic which continues to spread throughout the United States and the world. We are monitoring the outbreak of Covid-19 and the related business and travel restrictions and changes to behavior intended to reduce its spread, and its impact on our operations, financial position, cash flows, supply chains, and the industry in general, in addition to the impact on our employees. Due to the rapid development and fluidity of this situation, the magnitude and duration of the pandemic and its impact on our operations and liquidity is uncertain as of the date of this semiannual report.

The outbreak of Covid-19 could adversely impact our business, including delaying our nonclinical studies and clinical trials. We are still assessing our business operations and system supports and the impact Covid-19 may have on our results of operations and financial condition, but there can be no assurance that this analysis will enable us to avoid part or all of any impact from the spread of Covid-19 or its consequences, including downturns in business sentiment generally or in our sector in particular.

Our operations are located in Orange County, California and Tampa, Florida, and members of our senior management work in Atlanta, Georgia and New York, New York. We have been following the recommendations of local health authorities to minimize exposure risk for our employees, including the temporary closures of our offices and having employees work remotely to the extent possible, which has to an extent adversely affected their efficiency.

Our offices remain closed to non-essential employees based on the occupancy and social distancing orders from health authorities. Non-essential staff continue to work remotely utilizing secure remote access systems and technology infrastructure. We believe that we have adequate internal communications system and can remain operational with a remote staff.

Contractual Obligations

On May 1, 2016, we entered into a Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., as 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 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 \$5,000,000 in cash in exchange for our equity securities. Additionally, we are required to pay milestone payments on the due dates to the licensor for the license of the technology, as follows:

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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 prospectus. 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 the 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 will be increased upon such issuance. The amount of the increase will be determined by multiplying the number of shares then owned by the licensor by a fraction; the numerator of which will be equal to the number of shares of our common stock outstanding immediately after the issuance of additional shares of our common stock, and the denominator of which will be equal to the sum of (i) the number of shares of our common stock outstanding immediately prior to the issuance of additional shares of our common stock plus (ii) the number of shares of our common stock which the aggregate consideration for the total number of additional shares of our 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 LiProSaTM technology, pursuant to the terms of the Standard Exclusive license agreements with Sublicensing Terms, both dated June 21, 2018, (the "LiProSaTM license agreements") with the licensor and the University of South Florida. 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 LiProSaTM 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 our common stock equal to 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 the 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.

Recent Accounting Standards

For information about recent accounting pronouncements that may impact our financial statements, please refer to Note 3 of Notes to Financial Statements under the heading "Recent Accounting Standards."

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Company Overview

We are an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders. With our two current and future product candidates, we aim to bring treatments or cures to market at a reasonable cost as quickly as possible. Far too many individuals – patients and caregivers – suffer from the burden created by these devastating diseases. Our primary target, Alzheimer's disease, was among the most-feared diseases (second only to cancer) among Americans, according to a 2011 survey by the Harvard School of Public Health. Alzheimer's is also the sixth leading cause of death in the United States according to a 2020 Alzheimer's Disease Facts and Figures report by the Alzheimer's Association. To date, 5.8 million Americans suffer from Alzheimer's, which directly impacts more than 16 million Americans who provide an estimated 18.6 billion hours of unpaid care, valued at \$244 billion, according to data from the Alzheimer's Association. In 2020, the estimated healthcare costs for treating individuals with Alzheimer's in the United States was over \$305 billion, including \$206 billion in Medicare and Medicaid payments. These costs could rise as high as \$1.1 trillion by 2050 if no treatment or cure is found, the Alzheimer's Association reported.

Our current pipeline consists of two novel therapeutic drug candidates: (i) a patented ionic co-crystal technology delivering a therapeutic combination of lithium, proline and salicylate, known as AL001, through two royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc., as licensor, and (ii) 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 a patient's immunological system to combat Alzheimer's, known as AL002, through a royalty-bearing exclusive worldwide license from the same licensor.

Our lead candidate, AL001, is expected to provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's and other neurodegenerative diseases and psychiatric disorders. Based on nonclinical data, AL001 ionic 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 more than 35 years and human toxicology regarding lithium use has been well characterized, mitigating the potential regulatory burden for safety data. The results from one human cohort study by L.V. Kessing, et al., entitled "Does Lithium Protect Against Dementia?" published in the International Journal of Psychiatry and Neurosciences (January 2010) indicated that lithium had a preventive effect on the development of dementia in patients with bipolar disorder in comparison with anticonvulsants, antidepressants and antipsychotics. These findings suggest that lithium may exert some of its long-term beneficial effects in the treatment of affective disorders via underappreciated neuroprotective effects.

The results of randomized, placebo-controlled, clinical trials of lithium in the treatment of patients with Alzheimer's dementia and subjects with mild cognitive impairment have been widely published. Clinical studies have indicated that lithium administered at doses lower than those used for affective disorders can favorably impact Alzheimer's outcomes. A study by O.V. Forlenza, et al., entitled "Disease-Modifying Properties of Long-Term Lithium Treatment for Amnesic Mild Cognitive Impairment: Randomised Controlled Trial, appearing in the British Journal of Psychiatry (2011) reported that lithium was superior to a placebo, evidencing a slower decline of cognitive function as measured by the Alzheimer's Disease Assessment Scale cognitive subscale. Given the absence of adequate treatments for this highly prevalent disease, the potential efficacy of lithium in the long-term management of Alzheimer's may positively impact public health. There is an unmet medical need for safe and effective Alzheimer's treatments, particularly for treatments with neuroprotective properties.

There is increasing evidence to suggest that depressive illness, particularly in the elderly, is associated with neuronal cell loss. These findings suggest that lithium may exert some of its long-term beneficial effects in the treatment of affective disorders via underappreciated neuroprotective effects. Molecular biology and animal studies have also suggested that lithium may offer protection against Alzheimer's disease. Given the absence of other adequate treatments, the potential efficacy of lithium in the long-term treatment of neurodegenerative disorders may be warranted.

We submitted a Pre-Investigational New Drug (PIND) briefing package to the U.S. Food and Drug Administration (FDA) in July 2019 that argued against the need for any further preclinical safety studies. Pursuant to the FDA response letter, we believe the proposed test parameters for AL001 appear reasonable to support a Phase I study, thereby allowing us to conduct human clinical trials. Following Phase III clinical trials, we intend to seek approval to commercialize AL001 via a New Drug Application (NDA). We have been asked to provide a scientific bridge to a listed drug to support the adequacy of the nonclinical program. According to the FDA, the adequacy of the nonclinical data will be a matter for review. If the adequacy of the nonclinical data is not sufficient for the FDA, we will then be required to conduct a clinical pharmacokinetics animal study (an expected six week study) of AL001 to be considered for FDA approval. We received feedback from the FDA regarding the PIND briefing package and have begun the process of finalizing the Investigational New Drug (IND) application and, while FDA approval is not guaranteed, we expect to receive approval to begin a Phase I clinical trial with human subjects by March 31, 2021. While the FDA has not given us any indication as to whether AL001 will receive "breakthrough therapy" designation or be permitted to use the Section 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.

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We believe that our ability to re-engineer lithium solid dosage forms in order to optimize performance has the potential to address a wide range of clinical applications ranging from neurodegenerative disorders, such as Alzheimer's, amyotrophic lateral sclerosis (known as ALS), Huntington disease, multiple sclerosis, Parkinson's disease and traumatic brain injury, to more psychiatric conditions such as bipolar disorder, depression, mania, post-traumatic stress disorder and suicidality. This novel approach is intended to achieve the desired therapeutic outcome of enhanced penetration through the blood-brain barrier and sustained brain lithium concentrations while systemic exposures (and toxicities) are mitigated for other organ systems. The optimal modified-release lithium dosing approach should avoid acutely toxic peak concentrations in blood, as well as in the brain, and should maintain such blood concentrations for a predictable, clinically relevant time, with overall low systemic exposures that mitigate the potential for adverse events. The lithium delivery system would ideally be adaptable to a dosing regimen that maintains therapeutic brain lithium concentrations consistently for the longest possible time while allowing only modest exposures and providing adequate recovery periods between doses for other organ systems.

We have an additional preclinical candidate for Alzheimer's indication, AL002, which has transitioned from early-stage development to an extensive program of preclinical study and evaluation with an anticipated completion date of March 31, 2021. We plan to file an IND application with the FDA with respect to AL002 in the second quarter of 2021 and prepare to conduct a Phase I clinical trial in the third quarter of 2021.

Our Business Strategy

We intend to develop and commercialize therapeutics with the potential to significantly improve the lives of individuals afflicted by Alzheimer's and other neurodegenerative diseases and psychiatric disorders. To achieve these goals, we are pursuing the following key business strategies:

- **Advance clinical development of AL001 and AL002 for Alzheimer's treatment.** For our lead candidate, AL001, we have submitted a PIND briefing package to the FDA with proposed testing parameters and have begun the process to finalize an IND application. We intend to commence Phase I human clinical trials for AL001 in the first quarter of 2021. Our preclinical candidate, AL002, is in early stages of development. We intend to complete preclinical study and evaluation of AL002 in the first quarter of 2021 and commence Phase I human clinical trials in the third quarter of 2021.

- **Expand the development of AL001 and AL002 to include additional indications and delivery methods.** In addition to treating Alzheimer's, AL001 and AL002 have the potential to treat a wide range of neurodegenerative disorders. Other potential indications for AL001 include ALS, Huntington disease, multiple sclerosis, Parkinson's disease, bipolar disorder, depression, mania, post-traumatic stress disorder and suicidality. For AL002, we seek to mitigate adverse reactions experienced by patients' immunological systems in response to AL002 restoring immunological systems to combat Alzheimer's.

Focus on translational and functional endpoints to efficiently develop product candidates We believe AL001 is ideally positioned for a Section 505(b)(2) regulatory pathway for new drug approvals, which would grant us three to five years of market exclusivity. We also believe AL001 and AL002 are ideally positioned for breakthrough therapy designations, making them eligible to receive FDA approval in approximately four years.

Optimize the value of AL001 and AL002 in major markets. We intend to commercialize AL001 and AL002 by seeking marketing approval for both product candidates and partnering with biopharmaceutical companies seeking to strategically fortify pipelines and funding costly later-stage clinical development. 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.

Our Development Pipeline

The following chart provides an overview of the current development stages of our therapeutic product candidates.

Therapeutic Drug	Synopsis	Strength	Status
AL001	<ul style="list-style-type: none"> Use of patented Ionic Co-crystal (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 and Suicidality 	<ul style="list-style-type: none"> Exclusive license for Co-crystal delivery system for Alzheimer's and psychiatric indications Eligible for "breakthrough therapy" designation from FDA Seeking a Section 505(b)(2) clinical trial pathway from FDA Formulation may 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 	<ul style="list-style-type: none"> Filed Pre-IND in Q3 2019 Filing IND in Q1 2021 Commencing Phase I human clinical trials in Q1 2021
AL002	<ul style="list-style-type: none"> 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 preclinical trials including the highly publicized Elan study (AN-1972) 	<ul style="list-style-type: none"> Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of Alzheimer's Difficult to manufacture and hence not easily replicated by competitors Eligible for "breakthrough therapy" status via FDA Antibody responses induced after one inoculation (Preclinical) and lasted for four months Inflammation cytokines like IL1 and TNF.alpha, which are considered being related to inflammation did not increase with antibody level increase 	<ul style="list-style-type: none"> Completing preclinical studies Q1 2021 Filing IND in Q2 2021 Commencing Phase I human clinical trials in Q3 2021

Our Proprietary Technology

AL001 Drug Candidate

Our lead candidate, AL001, is expected to provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's and other neurodegenerative diseases and psychiatric disorders. Lithium salts have a long history of human consumption beginning in the 1800s. In psychiatry, they have been used to treat mania and as a prophylactic for depression since the mid-20th century. Today, lithium salts are used as a mood stabilizer for the treatment of bipolar disorder. Although the FDA has approved no medications as safe and effective treatments for suicidality, lithium has proven to be the only drug that consistently reduces suicidality in patients with neuropsychiatric disorders. Despite these effective medicinal uses, current FDA-approved lithium pharmaceuticals (lithium carbonate and lithium citrate) are limited by a narrow therapeutic window that requires regular blood monitoring of plasma lithium levels and blood chemistry by a clinician to mitigate adverse events. Because conventional lithium salts (carbonate and citrate) are eliminated relatively quickly, multiple administrations throughout the day are required to safely reach therapeutic plasma concentrations. 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.

Scientists from the University of South Florida have developed a new lithium co-crystal composition and method of preparation that allow for lower dosages to achieve therapeutic brain levels of lithium for psychiatric disorders, broadening lithium's therapeutic index. The compound offers improved physicochemical properties compared to existing forms of lithium, giving it the potential to be developed as an anti-suicidal drug or for use against mood disorders.

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. Results from recent clinical studies suggest that lithium treatment may reduce dementia development while preserving cognitive function and reducing biomarkers associated with Alzheimer's disease.

The team of inventors from the University of South Florida have specifically designed, synthesized and characterized the novel ionic co-crystal of lithium (AL001).

AL001 has been shown to exhibit improved nonclinical pharmacokinetics compared to current FDA-approved lithium products, and 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. Our preclinical studies concluded the following:

- Low doses of AL001 are safe and effective in reducing Alzheimer's pathology;
- AL001 has no effect on renal COX2 activity, a biomarker of renal toxicity, while markedly reducing abnormal beta-amyloid pathology, tau phosphorylation and neuro-inflammation;
- AL001 treatment did not induce tissue pathological damage in the heart, kidneys, liver and lungs by a general autopsy. In contrast, equimolar doses of lithium carbonate enhanced renal COX2 expression while having little or no impact on Alzheimer's pathology;
- AL001, 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;
- No significant differences in body weight, brain, heart, lungs, spleen, liver or kidneys were found between cohorts treated with AL001 and untreated cohorts;
- AL001 treatment improved cognitive function, as shown by lower escape latency during training and probe trial of the Morris water maze test and longer contextual freezing time during the fear conditioning test;
- AL001 treatment reduced depression, as assessed by tail suspension test, and irritability, as assessed by touch escape test;
- AL001 treatment afforded superior protection against cognitive impairment as determined by contextual fear conditioning test and irritability in comparison with lithium carbonate treatment; and
- Chronic AL001 treatment prevents cognitive deficits, depression, and irritability, and is superior in improving associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer's disease.

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 required by an NDA. Those drugs that qualify for the Section 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 Section 505(b)(2) regulatory pathway, AL001 would be eligible for three to five 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 approximately four years.

AL001 will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it or any successors are likely to 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 drug candidate 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 drug candidate, and we would be unable to continue our operations as currently planned.

AL002 Drug Candidate

The other patented solution that we have licensed to commercialize is 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. The proposed mechanism of action is through the pulsed-Dendritic Cell ("DC") activation of T-cells that yields to immune-based clearance of brain amyloid. Preclinical studies support that infusion with AL002-pulsed DC in transgenic mice is associated with lower amyloid burden and improved neurobehavioral performance. This is likely to be mediated by an anti-inflammatory effect in addition to the immunogenicity of this therapy.

AL002 is based on the theory that Alzheimer's symptoms are caused by plaque deposits composed of protein fragments called beta-amyloid that build up between nerve cells. One hypothesis is that a special type of immune cell, natural beta-amyloid antibodies, may play a role in preventing plaque build-up in people without Alzheimer's. As people age, their immune system may degrade, and some people may be unable to produce natural beta-amyloid antibodies which leads to the plaque build-up causing Alzheimer's disease.

AL002 is intended to elicit an immune response to produce anti-amyloid antibodies, which can then neutralize circulated beta-amyloid and prevent additional plaque build-up. The mutant antigen within AL002 was selected specifically for its high HLA binding affinity avoiding the need for an adjuvant, which may cause adverse (Th1) immune response.

AL002 is an autologous modified DC treatment. AL002 is a patient-specific therapy where the patient will undergo leukapheresis, a nonsurgical treatment used to reduce the quantity of white blood cells in the bloodstream, to isolate peripheral blood monocytes that are subsequently matured into DCs using an IL4+ GM-CSF cocktail. The DCs are incubated with a modified amyloid beta (A β) peptide (AL002 peptide) to sensitize them, and then administered to the same patient. Multiple preclinical studies and more than ten years of research have been conducted in preparation for this application.

Significant evidence has accumulated recently suggesting that immunotherapy is a highly promising modality of treatment in Alzheimer's. Most current immune-based active investigations are focused on passive immunization by pre-prepared A β antibody administration. Active immunization may offer additional or more lasting effect on the clearance of amyloid and a safer approach due to its reliance on autologous immune mechanisms. Further, preliminary evidence suggests a recurrence of the amyloid accumulation after clearance with the immunoglobulins. A prior attempt at engaging the immune system to treat Alzheimer's was conducted using the immunization with pre-aggregated synthetic A β (AN-1792) combined with the immunogenic adjuvant QS-21. The Phase IIa study with AN-1792 was terminated by the FDA due to severe meningoencephalitis in ~6% of vaccinated subjects. This was thought to be caused by the use of a strong non-specific antigenic determinant T-cell epitope in the A β 1-42 peptide and the inclusion of a QS21 adjuvant and polysorbate-80 stabilizing agent in the vaccine formulation.

Modified cell therapies, especially dendritic cells, may provide a safer and more patient-specific active immunization. Ex-vivo modification of DC as a modality of treatment has been previously used in oncological therapeutics. It has been shown to be relatively safe and is able to engage the immune system to attack the target tissues with success. Its use in Alzheimer's therapeutics is relatively recent. We are proposing to conduct a first-in-human Phase I study of autologous DC-pulsed with a modified A β epitope. Preclinical work supports that it is associated with positive anti-inflammatory response and a decrease in brain amyloid contents.

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 AL002 is ideally positioned for a breakthrough therapy designation. If we successfully acquire a breakthrough therapy designation for new drug approvals, we believe we can receive FDA approval for AL002 in approximately four years.

AL002 will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it or any successors are likely to 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 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 drug candidate 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 drug candidate, and we would be unable to continue our operations as currently planned.

Intellectual Property and Licensing Agreements

On May 1, 2016, we entered into the a Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc. (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” (AL002), filed April 7, 2009 and granted May 29, 2012.

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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 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 \$5,000,000 in cash in exchange for our equity securities. Additionally, we are required to pay milestone payments on the due dates to the Licensor for the license of the technology, as follows:

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

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 the Licensor will be increased upon such issuance. The amount of the increase will be determined by multiplying the number of shares of our common stock then owned by the Licensor by a fraction; the numerator of which will be equal to the number of shares of our common stock outstanding immediately after the issuance of additional shares of our common stock, and the denominator of which will be equal to the sum of (i) the number of shares of our common stock outstanding immediately prior to the issuance of additional shares of our common stock plus (ii) the number of shares of our common stock which the aggregate consideration for the total number of additional shares of our 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 AL001 technology, pursuant to the terms of the Standard Exclusive License Agreements with Sublicensing Terms, both effective July 2, 2018 (the “AL001 License Agreements”) with the licensor and the University of South Florida. In addition, a royalty payment of 3% is required pursuant to License #18110 while License #18111 requires a royalty payment of 1.5% on net sales of products developed from the licensed technology. For the two AL001 licenses, in the aggregate, we were required to pay initial license fees of \$50,000 no later than July 31, 2018, and \$150,000 no later than October 31, 2018. As an additional licensing fee, the Licensor is entitled to receive that number of shares of common stock equal to 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 the licensor for the license of the technology, as follows:

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

We have met the Pre-IND meeting milestone payment encompassing AL001. If we fail to meet a milestone payment by its specified date, the Licensor may terminate the License Agreement.

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On June 10, 2020, we obtained two additional royalty-bearing exclusive worldwide licenses from the Licensor to a therapy known as LiProSa™. One of the additional licenses is for the treatment of neurodegenerative diseases excluding Alzheimer’s disease and the other license is for the treatment of psychiatric diseases and

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 and effective *nunc pro tunc* November 1, 2019, with the Licensor and the University of South Florida (the “LiProSal™ License Agreements”). In addition, under each of the LiProSal™ License Agreements, 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, we are required to pay initial license fees of \$20,000 no later than November 1, 2020. Additionally, under each of the LiProSal™ License Agreements, we are required to pay milestone payments on the due dates to the 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

These license agreements have an indefinite term that continue until the later of the date no licensed patent under the applicable agreement remains a pending application or enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, or the date on which the licensee’s obligations to pay royalties expire under the applicable license agreement.

Market Opportunity

The Alzheimer’s Association estimates that the cost of caring for people with Alzheimer’s and other dementias will reach \$305 billion in 2020, including \$206 billion in Medicare and Medicaid payments, and that by 2050, these costs may rise as high as \$1.1 trillion. Currently, Alzheimer’s is the sixth leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. We were formed to develop and commercialize patented intellectual property and treatments for Alzheimer’s, by funding it from preclinical 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 the treatment of Alzheimer’s provide limited and transient effects on cognition. They cite projections of healthcare costs, including nursing home care, associated with Alzheimer’s and dementia (currently estimated to be in excess of \$640 billion for North America, Western Europe, and Asia-Pacific), that are continuing to grow based on data from the World Health Organization, Alzheimer’s International, the National Institute of Mental Health and the Lewy Body Dementia Association.

This medical shortfall puts a spotlight on an urgent need for development of new therapies capable of treating the estimated more than 45 million people worldwide suffering from Alzheimer’s today - 5.8 million in North America, 7.5 million in Western Europe, and 3.6 million in Asia-Pacific - a number expected to increase to more than 130 million by 2050. Alzheimer’s is the most common cause of dementia, estimated to be associated with some 60 to 70% of cases. An additional estimated 1.4 million patients in the United States 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.

Industry Overview

Currently, Alzheimer’s is the sixth leading cause of death in the United States 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, including \$206 billion in Medicare and Medicaid payments, 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, 1 in 10 persons over the age of 65 have Alzheimer’s, with more than 5.8 million Americans living with it. It is estimated that this number will increase to more than 14 million by 2050 if a cure is not found. Many Alzheimer’s related associations believe the actual number of adults with Alzheimer’s may be as much as five times more or 30 million since current statistics do not take in account deaths from complications or from related diseases like pneumonia or heart attack. These death certificates only list the most immediate cause. The fastest growing age group in the United States is the “over 85” group within which one in three individuals have Alzheimer’s. Women are 2½ times more likely to die from Alzheimer’s than from cancer.

Although deaths from other major causes have decreased significantly, official records indicate that deaths from Alzheimer’s have increased significantly. Between 2000 and 2018, the number of deaths from Alzheimer’s disease as recorded on death certificates has more than doubled, increasing 146%, while the number of deaths from the number one cause of death (heart disease) decreased 7.8%.

Every 65 seconds, someone in the United States develops Alzheimer’s. Of the ten 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. We were 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.

Alzheimer’s Disease

Alzheimer’s is a chronic neurodegenerative disorder affecting millions of people worldwide. It is the number one form of dementia in the world. The risk of being afflicted with Alzheimer’s increases with age, with one in ten people over the age of 65 having the disease. The prevalence of the disease is approximately 5.8 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. According to 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% (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% (32 of every 1,000 people), and for ages 85 and older (the “oldest-old”), the incidence was 7.6% (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. The Alzheimer’s Association estimates 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 2,444 clinical trials have been or are being conducted to find ways to treat

the disease, but it is unknown if any of the tested treatments will work.

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

Current clinical research focuses on the early phases of the disease. However, to our knowledge, no accurate and convenient tools are available today for pre-dementia diagnosis of Alzheimer’s to support these efforts. Currently Alzheimer’s is diagnosed as a clinical entity using a process that combines cognition assessments with imaging- and spinal-fluid 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.

Alzheimer’s Therapeutic Landscape



Reference: <https://alz-journals.onlinelibrary.wiley.com/cms/asset/2051f0be-b3d8-417f-8961-5c07f4b8ffb3/trc212050-gra-0001-m.jpg>

Current Drugs for Alzheimer’s Disease

There is a vast unmet need for effective pharmacological treatment for Alzheimer’s. Despite significant investments in drug discovery programs and strategies to treat Alzheimer’s, there have been no approved therapeutics developed that can boost cognition, alter the course of the disease, and provide long-term symptomatic improvement. There are currently four marketed drugs for the management of Alzheimer’s symptoms: donepezil, galantamine, and rivastigmine (all acting on cholinergic pathways) and memantine (targeting the NMDA receptor and glutamergic pathways). The long-term efficacy for these drugs has not been proven and they provide only temporary and modest clinical improvement.

Additionally, there are currently several experimental therapeutic agents for Alzheimer’s in various stages of development with clinical testing directed towards amyloid-beta, or Aβ, clearance, and inhibition of Tau protein aggregation or phosphorylated-Tau, or pTau, clearance. Recent clinical failures involving Aβ clearance highlight the incomplete understanding of the pathological processes in AD and clearly demonstrate the need for novel strategies to fight the disease.

Below is a chart outlining current treatments 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.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).

Clinical Management

We have retained TAMM Net, Inc., a ten-year old consulting firm based in Georgia for project management experienced with GMP to lead, develop and manage our preclinical and clinical efforts, extending from the current status of each product candidate through the exit or commercialization of the technologies that we have licensed. We may retain experienced Canadian and European Union consulting firms to commercialize these same technologies for these geographic markets.

Manufacturing

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

For AL001, we have selected Alcami, a U.S.-based contract development, testing and manufacturing organization, or CDMO, for pharma and biotech companies, headquartered in Wilmington, North Carolina, with major facilities in South Carolina, and Missouri. Alcami has over 40 year of providing CDMO services, has completed over 500 investigational new drug filings, supported over 50 product launches and work with over 200 molecules annually.

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 and 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 entering into partnering transactions with biopharmaceutical companies seeking to strategically fortify pipelines and funding 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 United States and in all major foreign countries.

Human Health Product Regulation in the United States

In the United States, 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, or IRB, a clinical hold on trials, a refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

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

The FDA's policies may change, and additional government regulations may be enacted that could prevent or delay regulatory approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States 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, or 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 into 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; and
- 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, or 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 is 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 the use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA or BLA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with current Good Manufacturing Practices, or 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 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, or 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, a REMS is 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, that is, the time between IND submission and NDA or BLA submission, and all of the review phase, or 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 United States Patent and Trademark Office, or 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 further 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 manufacturer 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, or 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 domestic regulations, we may eventually be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a process that requires the submission of a clinical trial application prior to the commencement of human clinical trials. In Europe, for example, a Clinical Trial Application, or 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 will be required to submit a marketing authorization application. This application is similar to the BLA in the United States, 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) the national authorization procedure.

The European Medicines Agency, or 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, at times referred to as the European Economic Area. The centralized procedure is compulsory for human drugs that: (i) are 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) are officially designated orphan drugs, and (iv) constitute 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 that 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 by the EMA is 210 days, though the date count stops whenever the Committee for Medicinal Products for Human Use, or 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 second half of 2022.

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

The principal 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 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 will update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all Member States, together with the approved summary of product characteristics, labeling and package leaflet. The concerned Member States then have 90 days to recognize the decision of the referenced Member State and the summary of product characteristics, labeling and package leaflet. National marketing authorizations will 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 will, 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, 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 United States, we are subject to complex laws and regulations pertaining to health care "fraud and abuse," including, but

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

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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 is also an increasing number of state laws that requires 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 United States, 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, or 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.

Our 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, salicylate and proline co-crystal technology from the University of South Florida.

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

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

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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 PTO that include our corporate name, Alzamend Neuro, two for our corporate slogan and one for our trade name.

Our 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.

Employees

As of December 29, 2020, we had one full-time employee (Stephan Jackman, our Chief Executive Officer) and three part-time employees. We also utilize independent consultants to assist us in our medical research and development projects.

Milton C. (Todd) Ault III, our Executive Chairman, Henry C.W. Nisser, our Executive Vice President and General Counsel, Kenneth S. Cragun, our Chief Financial Officer, and David Katzoff, our Chief Operating Officer, work for us on a part-time basis. Mr. Ault spends not less than an average of 8 hours per week, Mr. Nisser spends not less than an average of 8 hours per week, Mr. Cragun spends not less than an average of 10 hours per week, and Mr. Katzoff spends not less than an average of 8 hours per week on our company's business

Scientific Advisory Board

Our scientific advisory board of leading researchers in the neurodegenerative and neuropathology fields initially includes Dr. Thomas M. Wisniewski and Dr. Eric McDade.

Thomas M. Wisniewski, MD is a board-certified neurologist and neuropathologist and is the Director of the NYU Pearl Barlow Center for Memory Evaluation and Treatment who operates an active research laboratory focusing on neurodegenerative disorders with a particular focus on the mechanisms that drive amyloid deposition in Alzheimer's and prion diseases. This work has led to more than 300 peer-reviewed publications, 25 issued patents, and continuous funding from the NIH for over 26 years. Dr. Wisniewski's career has been dedicated to researching and developing treatments for numerous conditions including Alzheimer's disease, mild cognitive impairment, Lewy body dementia, frontotemporal dementia, prion disease, Jakob-Creutzfeldt disease, multiple system atrophy and memory loss. This has led him to receive numerous awards, honors and recognitions including being elected as a Distinguished Fellow in 2014, receiving the 2009 Prion Prize, the Alzheimer's Association Zenith Award in 2002 and being recognized every year by "Best Doctors in America" since 2008. Dr. Wisniewski has been an Associate Editor for the Journal of Alzheimer's Disease and Chief Editor of Frontiers in Aging Neuroscience since 2018. Dr. Wisniewski earned his M.D. degree at King's College London GKT School of Medical Education and completed his residencies and chief residencies in neurology and neuropathology at NYU School of Medicine and New York-Presbyterian/Columbia University Medical Center, respectively.

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Eric M. McDade, DO is a board-certified cognitive neurologist that has focused his activities on the evaluation of those with dementia syndromes and on developing a clinical research program that focuses on using brain imaging and cerebrospinal fluid markers to identify those at risk for Alzheimer disease. Currently, Dr. McDade is leveraging his clinical expertise to develop a cross-disciplinary team that combines neuroimaging, clinical evaluations and basic science to better explore and translate work in the use of imaging and fluid biomarkers to better understand the timing and relationship between measures of disease risk and progression. The goal of this work is to identify better measures and target for interventions and prevention for Alzheimer's disease and has led to more than 76 peer-reviewed publications and continuous funding from the NIH for over ten years. Additionally, Dr. McDade is the Associate Director of the Dominantly Inherited Alzheimer Trials Unit (DIAN-TU). The DIAN-TU is a global network of families at risk for a genetic form of Alzheimer's and is pioneering prevention trials for this young-onset for Alzheimer's. Dr. McDade earned his doctorate at Chicago College of Osteopathic Medicine and a B.A. degree in Psychology from Canisius College. Dr. McDade completed an internship at the University of Illinois College of Medicine in Chicago and his residency at the University of Maryland. Dr. McDade received his certification of Neurology from the American Board of Psychiatry and Neurology and Behavioral Neurology from the United Council of Neurologic Subspecialties.

We entered into consulting agreements with Drs. Wisniewski and McDade on February 1, 2019 and May 1, 2019, respectively. The annual cash compensation under the consulting agreements consists of \$12,000 per scientific advisory board member and stock options to purchase 50,000 shares at \$1.00 per share with a three-year term, vesting over two years.

Facilities

We currently maintain our corporate offices at the University of South Florida's Incubator Center located in Tampa, Florida, where we utilize shared labs and extensive research resources. Our total rent expense for this office and testing space is \$918 per month. We believe our present space is adequate for our current operations. Following this offering, we intend to search for suitable office space to accommodate near-term planned expansion.

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. Currently, there are no material legal proceedings or arbitration proceedings currently pending against our company.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth the names and ages of our executive officers, directors and director nominees, and their positions with us, as of December 29, 2020:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Milton C. (Todd) Ault III	50	Executive Chairman of the Board
Stephan Jackman	45	Chief Executive Officer and Director
Henry C.W. Nisser	52	Executive Vice President, General Counsel and Director
Kenneth S. Cragun	60	Chief Financial Officer
David Katzoff	59	Chief Operating Officer
William B. Horne	52	Director
Philip E. Mansour	53	Director
Virginia Lazala	59	Director nominee
Jeffrey Oram	53	Director nominee

Ms. Lazala and Mr. Oram have agreed to join our Board of Directors upon the closing of this offering.

The following information provides a brief description of the business experience of each executive officer, director and director nominee.

Milton C. (Todd) Ault III founded our company and has served as our Chairman of the Board since inception and as our Executive Chairman since November 2018. Mr. Ault is a seasoned business professional and entrepreneur who has spent more than 27 years identifying value in various financial markets including equities, fixed income, commodities and real estate. In March 2017, Mr. Ault was appointed Executive Chairman of the Board of DPW Holdings, Inc. (“DPW”) and, in December 2017, Mr. Ault was appointed Chief Executive Officer of DPW. Mr. Ault has served as Chairman of Ault & Company, a holding company since December 2015, and as Chairman of Avalanche International Corp., a publicly traded company (“Avalanche”), 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 with many publicly traded and privately held companies, which range from development stage to mature 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 a director of our company.

Stephan Jackman joined our company as Chief Executive Officer in November 2018. Mr. Jackman was elected as a director in September 2020. 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. Prior to joining our company, from October 2017 to November 2018, Mr. Jackman was the Chief Operating Officer of Ennaid Therapeutics, an emerging biopharmaceutical company focusing on cures for mosquito borne infectious diseases such as Zika and Dengue viruses. Mr. Jackman was Chief Operating Officer of Exit 9 Technologies from October 2015 to October 2017, a technology startup with a digital platform that connects retailers, publisher and customers. Additionally, from August 2014 to October 2015, he was an independent project and management consultant assisting startups, Fortune 500 companies and non-profits with major strategic initiatives. He has also held positions of increasing responsibility at Novartis Pharmaceuticals Corporation, L’Oréal USA, SBM Management Services and Family Intervention Services. Mr. Jackman holds a Master of Science in Management and a Bachelor of Engineering in Mechanical Engineering from Stevens Institute of Technology. Mr. Jackman’s 15 years of experience in life sciences and growth companies, day-to-day operational leadership of our company and in-depth knowledge of our drug candidates make him well qualified as a member of the Board.

Henry C.W. Nisser has served as our Executive Vice President and General Counsel on a part-time basis since May 2019. Mr. Nisser was appointed as a director in September 2020. Since May 2019, Mr. Nisser has served as the Executive Vice President and General Counsel of DPW and as one of its directors since September 2020. Mr. Nisser is the Executive Vice President and General Counsel of Avalanche. From October 2011 through April 2019, Mr. Nisser was an associate and subsequently a partner with Sichenzia Ross Ference LLP, a law firm in New York. While with this law firm, his practice was concentrated on 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 is fluent in French and Swedish, as well as conversant in Italian. Mr. Nisser received his B.A. degree from Connecticut College, where he majored in International Relations and Economics. He received his LL.B. from University of Buckingham School of Law in the United Kingdom. We believe that Mr. Nisser’s extensive legal experience involving complex transactions and comprehensive knowledge of securities laws and corporate governance requirements applicable to listed companies give him the qualifications and skills to serve as one of our directors.

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Kenneth S. Cragun joined our company on a part-time basis in December 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 Chief Financial Officer of CorVel Corporation, a publicly traded company 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 Chief Financial Officer 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 and serves on the Board of Directors and Chairman of the Audit Committee of Verb Technology Company, Inc. Mr. Cragun began his professional career at Deloitte. Mr. Cragun holds a Bachelor of Science degree in accounting from Colorado State University-Pueblo.

David Katzoff joined our company on a part-time basis in November 2019, serving as our Senior Vice President of Operations from November 2019 to December 2020, and currently serves as our Chief Operating Office since December 2020. Mr. Katzoff has served as Senior Vice President of Finance of DPW Holdings, Inc. since January 2019. From 2015 to 2018, Mr. Katzoff served as Chief Financial Officer of Lumina Media, LLC, a privately-held media company and publisher of life-style publications. From 2003 to 2017, Mr. Katzoff served a Vice President of Finance of Local Corporation, a publicly-held local search company. Mr. Katzoff received a B.S. degree in Business Management from the University of California at Davis.

William B. Horne has served as a director of our company since June 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. In January 2018, Mr. Horne was appointed as DPW’s Chief Financial Officer until August 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. 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. Mr. Horne served as the Chief Financial Officer of Patient Safety Technologies, Inc., a medical device company, 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. Mr. Horne holds a B.A. degree 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.

Philip E. Mansour has been a director of our company since April 2016. He has served as a director and as the President and Chief Executive Officer of Avalanche since May 2014. Mr. Mansour was the Chief Executive Officer of our company from 2016 through 2018. Mr. Mansour worked as Principal with the PMC Solutions organization from 2002 to 2018. The organization provided consulting services to small and medium size organizations in the areas of disruptive technology, strategic planning, organizational change management, business development and financing. He also served as Vice President, Corporate Development for Conceivex, Inc., a private company focused on At-Home Infertility treatment, from 2006 to 2011. Mr. Mansour’s prior experience includes leading the research and development for several prominent educational technology companies for more than two decades and leading large government grants with leading universities. We believe that Mr. Mansour, given his entrepreneurial and significant corporate experience and general business background demonstrates he has the qualifications to serve as one of our directors.

Virginia Lazala has agreed to join our Board of Directors upon the closing of this offering. Ms. Lazala is Vice President and Legal Head for the LACan (Latin America and Canada) Region and for Human Resources for Novartis Oncology, a global business unit within Novartis Pharmaceuticals Corporation. Ms. Lazala has been with the Novartis group of companies since February 2000, having joined the company from Hudson United Bank, where she had been Senior Vice President and Bank Counsel from 1998. Since joining Novartis, Ms. Lazala has held various positions of increasing responsibility. From 2002 to 2005, Ms. Lazala served as General Counsel for Novartis Animal Health, Inc., and progressed through Novartis Pharmaceuticals to her current role as a Vice President of that company. Ms. Lazala holds a B.A. degree in economics and political science from Wellesley College and a J.D. degree from Georgetown University. We believe that Ms. Lazala’s extensive financial, legal and pharmaceutical experience gives her the qualifications and skills to serve as one of our directors.

Jeffrey Oram has agreed to join our Board of Directors upon the closing of this offering. Mr. Oram is a business professional with more than 25 years of corporate,

private and institutional investment experience. Mr. Oram has spent the last 13 years in the institutional real estate capital markets. Since 2016, he has been a Principal at Godby Realtors, a private real estate investment and brokerage firm. From 2010 to 2018, Mr. Oram served as an Executive Member of the New Jersey State Investment Council, which oversees the investment of the State of New Jersey's \$80 billion pension fund. From 2011 to 2016, he served as Executive Managing Director at Colliers International, from 2009 to 2011 he served as Director at Marcus and Millichap, and from 2003 to 2009, served as First Vice President at CB Richard Ellis. Mr. Oram received a Bachelor of Science degree in biology from Princeton University. We believe that Mr. Oram's 25 years of corporate, private and institutional investment experience gives him the qualifications and skills to serve as one of our directors.

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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. In November 2018, the Board adopted charters that establish an Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. Each of the Board committees will provide risk oversight in respect of its areas of concentration and report material risks to the Board for further consideration.

Term of Office

Directors serve until the next annual meeting of our stockholders and until their successors are elected and qualified. Officers are appointed to serve at the discretion of our Board of Directors.

Director Independence

We use the definition of "independence" of the NYSE American to make this determination. Section 803A(2) of the NYSE American Company Guide 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. Section 803A(2) generally provides 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 is an immediate family member of an individual who is, or at any time during the past three years was, employed by the company as an executive officer;
- 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 this definition, we currently have no independent directors. We are presently in the process of identifying and selecting qualified independent and diverse directors for our Board of Directors, who will comprise a majority of all members of the Board.

Family Relationships

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

Involvement in Certain Legal Proceedings

Except as set forth below, to the best of our knowledge, during the past ten years, none of the following occurred with respect to a present or former director, executive officer or employee:

- 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;

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- 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. Ault held series 7, 24 and 63 licenses and managed four domestic hedge funds and one bond fund from 1998 through 2008. In April 2012, as a result of an investigation by FINRA involving activities during 2008, Mr. Ault agreed to a settlement with FINRA in which he did not admit to any liability or violation of any laws or regulatory rules and that included restitution and a suspension from association with a FINRA member firm for a period of two years. As part of that settlement, Mr. Ault agreed that before he would reapply for association with FINRA, if at all, he would make restitution to certain investors. Mr. Ault was able to speak with and pay restitution to one of the investors, but no others. As a result, Mr. Ault is neither eligible, nor does he intend, to apply for association with FINRA.

Mr. Cragun served as Chief Financial Officer of Local Corporation (April 2009 to September 2016), which, in June 2015, filed a voluntary petition in the U.S. 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 disclosed 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.

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.

Board Committees

Our Board of Directors has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The responsibilities of the Audit Committee (which, upon completion of this offering, will consist of Messrs. _____ (Chair), _____ and _____) include recommending to the Board of Directors the firm of independent accountants to be retained by our company, reviewing with our independent accountants the scope and results of their audits, and reviewing with the independent accountants and management our accounting and reporting principles, policies and practices, as well as our accounting, financial and operating controls and staff. The Compensation Committee (which, upon completion of this offering, will consist of Messrs. _____ (Chair) and _____) has responsibility for establishing and reviewing employee compensation. The Compensation Committee also has responsibility for administering and interpreting the Alzamend Neuro, Inc. 2020 Stock Incentive Plan, and determining the recipients, amounts and other terms (subject to the requirements of the Plan) of stock options and other equity-based awards which may be granted under the 2020 Stock Incentive Plan from time to time. The purpose of the Nominating and Corporate Governance Committee (which, upon completion of this offering, will consist of Messrs. _____ (Chair) and _____) is to select, or recommend for our entire Board’s selection, the individuals to stand for election as directors at the annual meeting of stockholders, as well as to consider the adequacy of our corporate governance and oversee and approve management continuity planning processes.

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EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth summary compensation information for the following persons: (i) all persons serving as our principal executive officer during the years ended April 30, 2020 and 2019, and (ii) our two other most highly compensated executive officers who received compensation during the years ended April 30, 2020 and 2019 of at least \$100,000 and who were executive officers on April 30, 2020. We refer to these persons as our “named executive officers” in this prospectus. The following table includes all compensation earned by the named executive officers for the respective period, regardless of whether such amounts were actually paid during the period:

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾	All Other Compensation (\$)	Total (\$)
Stephan Jackman	2020	200,000			1,946,130		2,146,130
Chief Executive Officer	2019	50,000			3,356,289		3,406,289
Kenneth S. Cragun	2020	86,667			973,065		1,059,723
Chief Financial Officer	2019	20,000			1,091,700		1,111,700
Henry C.W. Nisser	2020	50,000			802,366		852,366
Executive Vice President and General Counsel	2019	0	0	0	0		

(1) The values reported in the “Option Awards” 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 a Master Services Agreement entered into with Avalanche, a related party, on May 1, 2016. Pursuant to the terms of that agreement, Avalanche provided management, consulting and financial services to our company. Such services included advice and assistance concerning all aspects of operations, planning and financing of our company and conducting relations with accountants, attorneys, financial advisors and other professionals. The term of the Master Services Agreement, as amended, was for the period from 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 year ended April 30, 2019, we paid \$160,000 in management fees. At April 30, 2020 and April 30, 2019, \$58,333 and \$75,000, respectively, was included within related party payable on our balance sheet. The Master Services Agreement was terminated as of December 31, 2018.

Employment Agreements

Stephan Jackman. In November 2018, we entered into an offer letter with Stephan Jackman to serve as our Chief Executive Officer for a period of four years. For his services, Mr. Jackman is currently paid a base salary of \$225,000 and is 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, will 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; and

Mr. Jackman received a stock option to purchase 5,000,000 shares of our common stock exercisable for a period of ten years from November 16, 2018, at a per share price of \$1.00, which option will vest as follows:

- 3,000,000 shares of our common stock will vest in equal increments over 48 months beginning on November 16, 2018;
- 1,000,000 shares of our common stock will vest upon approval by the FDA of an NDA for AL001 in equal increments over 36 months from November 1, 2018; and
- 1,000,000 shares of our common stock will vest upon approval by the FDA of an NDA for AL002 in equal increments over 48 months from November 1, 2018.

In November 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 our initial public offering of 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 of the stock price milestones are not achieved within three years, the unvested portion of the performance options will be reduced by 25%.

Kenneth S. Cragun. In November 2018, we entered into an offer letter with Kenneth S. Cragun to serve as our Chief Financial Officer for a period of four years. For his services, Mr. Cragun is paid a base salary of \$100,000 per year, which amount 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 will 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, will in part be determined based upon the successful attainment of the same milestones as are applicable for Mr. Jackman.

Mr. Cragun received a stock option to purchase 1,500,000 shares of our common stock exercisable for a period of ten years from December 15, 2018 at a per share price of \$1.00. The option will vest in equal increments over 48 months beginning on December 15, 2018; however, 500,000 shares of our 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.

In November 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 our initial public offering of 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%.

Henry Nisser. In May 2019, we entered into a four-year employment agreement with Henry C.W. Nisser to serve as our Executive Vice President and General Counsel. For his services, Mr. Nisser is paid a base salary of \$50,000 per year and is 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.

Mr. Nisser received a stock option to purchase 1,250,000 shares of our common stock exercisable for a period of five years at an exercise price of \$1.50 per share. The shares of our common stock underlying the option vest in equal monthly installments over the 48 months beginning on June 1, 2019.

Outstanding Equity Awards at Fiscal Year End

The following table provides information on outstanding equity awards as of April 30, 2020 awarded to our named executive officers.

OUTSTANDING EQUITY AWARDS AT APRIL 30, 2020

Name	OPTION AWARDS				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Stephan Jackman	0	1,000,000	1,000,000	\$1.00	11/1/2021
	0	1,000,000	1,000,000	\$1.00	11/1/2022
	1,062,500	1,937,500	0	\$1.00	11/16/2028
	0	2,000,000	2,000,000	\$1.50	11/18/2029
Kenneth S. Cragun	500,000	1,000,000	0	\$1.00	12/15/2028
	0	1,000,000	1,000,000	\$1.50	11/18/2029
Henry C.W. Nisser	286,462	963,538	0	\$1.00	5/1/2029

Incentive Compensation Plans

2016 Stock Incentive Plan

In April 2016, our stockholders approved our company's 2016 Stock Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of a maximum of 12,500,000 shares of our common stock to be offered to our directors, officers, employees and consultants. On March 1, 2019, our stockholders approved an additional 7,500,000 shares to be available for issuance under the 2016 Plan. Options granted under the 2016 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 ten years from the date of grant. Restricted stock awards granted under the 2016 Plan are subject to a vesting period determined at the date of grant.

2020 Stock Incentive Plan

In _____ 2020, our Board of Directors adopted, and our stockholders approved, the Alzamend Neuro, Inc. 2020 Stock Incentive Plan (the “2020 Plan”). The 2020 Plan authorizes the grant to eligible individuals of (1) stock options (incentive and non-statutory), (2) restricted stock, (3) stock appreciation rights, or SARs, (4) restricted stock units, and (5) other stock-based compensation.

Stock Subject to the 2020 Plan. The maximum number of shares of our common stock that may be issued under the 2020 Plan is 10,000,000 shares, which number will be increased to the extent that compensation granted under the 2020 Plan is forfeited, expires or is settled for cash (except as otherwise provided in the 2020 Plan). Substitute awards (awards made or shares issued by us in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company that we acquire or any subsidiary of ours or with which we or any subsidiary combines) will not reduce the shares authorized for grant under the 2020 Plan, nor will shares subject to a substitute award be added to the shares available for issuance or transfer under the 2020 Plan.

No Liberal Share Recycling. Notwithstanding anything to the contrary, any and all stock that is (i) withheld or tendered in payment of an option exercise price; (ii) withheld by us or tendered by the grantee to satisfy any tax withholding obligation with respect to any award; (iii) covered by a SAR that it is settled in stock, without regard to the number of shares of stock that are actually issued to the grantee upon exercise; or (vi) reacquired by us on the open market or otherwise using cash proceeds from the exercise of options, will not be added to the maximum number of shares of stock that may be issued under the 2020 Plan.

Eligibility. Employees of, and consultants to, our company or our affiliates and members of our Board of Directors are eligible to receive equity awards under the 2020 Plan. Only our employees, and employees of our parent and subsidiary corporations, if any, are eligible to receive incentive stock options. Employees, directors (including non-employee directors) and consultants of or for our company and our affiliates are eligible to receive non-statutory stock options, restricted stock, purchase rights and any other form of award the 2020 Plan authorizes.

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Purpose. The purpose of the 2020 Plan is to promote the interests of our company and our stockholders by providing executive officers, employees, non-employee directors, and key advisors of our company and our subsidiaries with appropriate incentives and rewards to encourage them to enter into and remain in their positions with us and to acquire a proprietary interest in our long-term success, as well as to reward the performance of these individuals in fulfilling their personal responsibilities for long-range and annual achievements.

Administration. Unless otherwise determined by the Board of Directors, the Compensation Committee administers the 2020 Plan. The Compensation Committee is composed solely of “non-employee directors” within the meaning of Rule 16b-3 under the Exchange Act, “outside directors” within the meaning of Section 162(m) of the Internal Revenue Code, and “independent directors” within the meaning of NYSE American listing standards. The Compensation Committee has the power, in its discretion, to grant awards under the 2020 Plan, to select the individuals to whom awards are granted, to determine the terms of the grants, to interpret the provisions of the 2020 Plan and to otherwise administer the 2020 Plan. Except as prohibited by applicable law or any rule promulgated by a national securities exchange to which the Company may in the future be subject, the Compensation Committee may delegate all or any of its responsibilities and powers under the 2020 Plan to one or more of its members, including, without limitation, the power to designate participants and determine the amount, timing and term of awards under the 2020 Plan. In no event, however, will the Compensation Committee have the power to accelerate the payment or vesting of any award, other than in the event of death, disability, retirement or a change of control of our company.

The 2020 Plan provides that members of the Compensation Committee will be indemnified and held harmless by us from any loss or expense resulting from claims and litigation arising from actions related to the 2020 Plan.

Term. The 2020 Plan was effective as of December XX, 2020, and awards may be granted through December XX, 2030. No awards may be granted under the 2020 Plan subsequent to that date. The Board of Directors may suspend or terminate the 2020 Plan without stockholder approval or ratification at any time or from time to time.

Amendments. Subject to the terms of the 2020 Plan, the Compensation Committee, as administrator, has the sole discretion to interpret the provisions of the 2020 Plan and outstanding awards. Our Board of Directors generally may amend or terminate the 2020 Plan at any time and for any reason, except that no amendment, suspension or termination may impair the rights of any participant without his or her consent, and except that approval of our stockholders is required for any amendment which, among provisions, increases the number of shares of common stock subject to the 2020 Plan, decreases the price at which grants may be granted and reprices existing options.

Repricing Prohibition. Other than in connection with certain corporate events, the Compensation Committee will not, without the approval of our stockholders, (a) lower the option price per share of an option or SAR after it is granted, (b) cancel an option or SAR when the exercise price per share exceeds the fair market value of one share in exchange for cash or another award (other than in connection with a change of control), or (c) take any other action with respect to an option or SAR that would be treated as a repricing under the rules and regulations of the principal U.S. national securities exchange on which our shares are then listed.

Minimum Vesting Requirement. Grantees of full-value awards (i.e., awards other than options and SARs), will be required to continue to provide services to us or an affiliated company) for not less than one-year following the date of grant in order for any such full-value awards to fully or partially vest (other than in case of death, disability or a Change of Control). Notwithstanding the foregoing, up to 5% of the available shares of stock authorized for issuance under the 2020 Plan may provide for vesting of full-value awards, partially or in full, in less than one year.

Adjustments upon Changes in Capitalization. In the event of any merger, reorganization, consolidation, recapitalization, dividend or distribution (whether in cash, shares or other property, other than a regular cash dividend), stock split, reverse stock split, spin-off or similar transaction or other change in our corporate structure affecting our common stock or the value thereof, appropriate adjustments to the 2020 Plan and awards will be made as the Board of Directors determines to be equitable or appropriate, including adjustments in the number and class of shares of stock available for issuance under the 2020 Plan, the number, class and exercise or grant price of shares subject to awards outstanding under the 2020 Plan, and the limits on the number of awards that any person may receive.

Change of Control. Agreements evidencing awards under the 2020 Plan may provide that upon a Change of Control (as defined in the 2020 Plan), unless otherwise provided in the agreement evidencing an award), outstanding awards may be cancelled and terminated without payment if the consideration payable with respect to one share of Stock in connection with the Change of Control is less than the exercise price or grant price applicable to such award, as applicable.

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Notwithstanding any other provisions of the 2020 Plan to the contrary, the vesting, payment, purchase or distribution of an award may not be accelerated by reason of a Change of Control for any participant unless the Grantee’s employment is involuntarily terminated as a result of the Change of Control as provided in the Award agreement or in any other written agreement, including an employment agreement, between us and the participant. If the Change of Control results in the involuntary termination of participant’s employment, outstanding awards will immediately vest, become fully exercisable and may thereafter be exercised.

Generally, under the 2020 Plan, a Change of Control occurs upon (i) the consummation of a reorganization, merger or consolidation of our company with or into another entity, pursuant to which our stockholders immediately prior to the transaction do not own more than 50% of the total combined voting power after the transaction, (ii) the consummation of the sale, transfer or other disposition of all or substantially all of our assets, (iii) certain changes in the majority of our Board of Directors from those in office on the effective date of the 2020 Plan, (iv) the acquisition of more than 50% of the total combined voting power in our outstanding securities by any person, or (v) we are dissolved or liquidated.

Types of Awards

Stock Options. Incentive stock options and non-statutory stock options are granted pursuant to award agreements adopted by our Compensation Committee. Our Compensation Committee determines the exercise price for a stock option, within the terms and conditions of the 2020 Plan; provided, that the exercise price of an incentive stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified by our Compensation Committee.

The Compensation Committee determines the term of stock options granted under the 2020 Plan, up to a maximum of 10 years, except in the case of certain Incentive Stock Options, as described below. The Compensation Committee will also determine the length of period during which an optionee may exercise their options if an optionee's relationship with us, or any of our affiliates, ceases for any reason; for incentive stock options, this period is limited by applicable law. The Compensation Committee may extend the exercise period in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term unless the term is extended in accordance with applicable law.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the Compensation Committee and may include (a) cash or its equivalent, (b) delivering a properly executed notice of exercise of the option to us and a broker, with irrevocable instructions to the broker promptly to deliver to us the amount necessary to pay the exercise price of the option, (c) any other form of legal consideration that may be acceptable to the Compensation Committee or (d) any combination of (a), (b) or (c).

Unless the Compensation Committee provides otherwise, options are generally transferable in accordance with applicable law, provided that any transferee of such options agrees to become bound by the terms of the 2020 Plan. An optionee may also designate a beneficiary who may exercise the option following the optionee's death.

Incentive or Non-statutory Stock Options. Incentive stock options may be granted only to our employees, and the employees of our parent or subsidiary corporations, if any. The Compensation Committee may grant awards of incentive or non-statutory stock options that are fully vested on the date made, to any of our employees, directors or consultants. Option awards are granted pursuant to award agreements adopted by our Compensation Committee. To the extent required by applicable law, the aggregate fair market value, determined at the time of grant, of shares of our Common Stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year may not exceed \$100,000. To the extent required by applicable law, no incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (a) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (b) the term of the incentive stock option does not exceed five years from the date of grant.

Stock Appreciation Rights. An SAR is the right to receive stock, cash, or other property equal in value to the difference between the grant price of the SAR and the market price of our common stock on the exercise date. SARs may be granted independently or in tandem with an option at the time of grant of the related option. An SAR granted in tandem with an option will be exercisable only to the extent the underlying option is exercisable. An SAR confers on the grantee a right to receive an amount with respect to each share of common stock subject thereto, upon exercise thereof, equal to the excess of (A) the fair market value of one share of common stock on the date of exercise over (B) the grant price of the SAR (which in the case of an SAR granted in tandem with an option will be equal to the exercise price of the underlying option, and which in the case of any other SAR will be such price as the Compensation Committee may determine but in no event will be less than the fair market value of a share of common stock on the date of grant of such SAR).

Restricted Stock and Restricted Stock Units. Restricted stock is common stock that we grant subject to transfer restrictions and vesting criteria. A restricted stock unit is a right to receive stock or cash equal to the value of a share of stock at the end of a specified period that we grant subject to transfer restrictions and vesting criteria. The grant of these awards under the 2020 Plan are subject to such terms, conditions and restrictions as the Compensation Committee determines consistent with the terms of the 2020 Plan.

At the time of grant, the Compensation Committee may place restrictions on restricted stock and restricted stock units that will lapse, in whole or in part, only upon the attainment of performance goals; provided that such performance goals will relate to periods of performance of at least one fiscal year, and if the award is granted to a 162(m) officer, the grant of the award and the establishment of the performance goals will be made during the period required under Internal Revenue Code Section 162(m). Except to the extent restricted under the award agreement relating to the restricted stock, a grantee granted restricted stock will have all of the rights of a stockholder, including the right to vote restricted stock and the right to receive dividends.

Unless otherwise provided in an award agreement, upon the vesting of a restricted stock unit, there will be delivered to the grantee, within 30 days of the date on which such award (or any portion thereof) vests, the number of shares of Common Stock equal to the number of restricted stock units becoming so vested.

Other Stock-Based Awards. The 2020 Plan also allows the Compensation Committee to grant "Other Stock-Based Awards," which means a right or other interest that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, common stock. Subject to the limitations contained in the 2020 Plan, this includes, without limitation, (i) unrestricted stock awarded as a bonus or upon the attainment of performance goals or otherwise as permitted under the 2020 Plan and (ii) a right to acquire stock from us containing terms and conditions prescribed by the Compensation Committee. At the time of the grant of other stock-based awards, the Compensation Committee may place restrictions on the payout or vesting of other stock-based awards that will lapse, in whole or in part, only upon the attainment of performance goals; provided that such Performance Goals will relate to periods of performance of at least one fiscal year, and if the award is granted to a 162(m) Officer, the grant of the Award and the establishment of the performance goals will be made during the period required under Internal Revenue Code Section 162(m). Other Stock-Based Awards may not be granted with the right to receive dividend equivalent payments.

Performance Awards. Performance awards provide participants with the opportunity to receive shares of our common stock, cash or other property based on performance and other vesting conditions. Performance awards may be granted from time to time as determined at the discretion of the Board, or the Compensation Committee (as applicable). Subject to the share limit and maximum dollar value set forth above under "Limits per Participant," the Board, or the Compensation Committee (as applicable), has the discretion to determine (i) the number of shares of common stock under, or the dollar value of, a performance award and (ii) the conditions that must be satisfied for grant or for vesting, which typically will be based principally or solely on achievement of performance goals.

Performance Criteria. With respect to awards intended to qualify as performance-based compensation under Code Section 162(m), a committee of "outside directors" (as defined in Code Section 162(m)) with authority delegated by our Board will determine the terms and conditions of such awards, including the performance criteria. The performance goals for restricted stock awards, restricted stock units, performance awards or other share-based awards will be based on the attainment of specified levels of, among other metrics, the attainment of certain target levels of, or a specified percentage increase in, revenues, earnings, income before taxes and extraordinary items, net income, operating income, earnings before or after deduction for all or any portion of income tax, earnings before interest, taxes, depreciation and amortization or a combination of any or all of the foregoing.

The performance goals may be based solely by reference to our performance or the performance of one or more of our subsidiaries, parents, divisions, business segments or business units, or based upon the relative performance of other companies or upon comparisons of any of the indicators of performance relative to other companies. The authorized committee of outside directors may also exclude under the terms of the performance awards, the impact of an event or occurrence that the committee determines should appropriately be excluded, including restructurings, discontinued operations, extraordinary items, and other unusual or non-recurring charges, or changes in generally accepted accounting principles or practices.

Director Compensation

Following the effective date of this offering, we will pay each independent director an annual base amount of \$_____. Our Board may make recommendations for adjustments to an independent director's compensation when the level of services provided are significantly above what was anticipated.

Prior to the date of this prospectus, no members of our Board of Directors were considered independent and, accordingly, no director compensation has been paid to date to members of our Board.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Certain Relationships

Our company is controlled by Milton C. (Todd) Ault III, our Executive Chairman, directly and through his controlling interest in Ault Life Sciences, Inc. and Ault Life Sciences Fund, LLC. Mr. Ault is also the Chairman, Chief Executive Officer and single largest stockholder (through Ault & Company, Inc.) of DPW Holdings, Inc. ("DPW"). The Board of Directors and executive officers of our company and the board of directors and executive officers of DPW contain some of the same individuals. William B. Horne, a director of our company, is the President and a director of DPW, Henry C.W. Nisser, our Executive Vice President, General Counsel and a director of our company, holds the same positions in DPW, and Kenneth S. Cragun, our Chief Financial Officer is the Chief Financial Officer of DPW. Additionally, Mr. Ault is the Chairman of Avalanche International Corp. dba MTIX International ("Avalanche"), of which Mr. Horne is a director and its Chief Financial Officer, Mr. Nisser is its Executive Vice President and General Counsel, and Philip E. Mansour, a director of our company, is Avalanche's President, Chief Executive Officer and a director.

Transactions with Related Persons

To the best of our knowledge, from inception to our most recent fiscal year end on April 30, 2020, other than as set forth below, 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 1% 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).

On May 1, 2016, we entered into a Master Services Agreement with Avalanche International Corp., a related party. Messrs. Ault, Horne and Mansour are officers and directors of Avalanche. Further, MCKEA Holdings, LLC ("McKEA"), of which Mr. Ault's spouse is the managing member, is the majority member of Philou Ventures, LLC, which is the controlling shareholder of Avalanche. Pursuant to the terms of the Master Services Agreement, Avalanche provided management, consulting and financial services to our company. Such services included advice and assistance concerning all aspects of operations, planning and financing of our company and conducting relations with accountants, attorneys, financial advisors and other professionals. The term of the Master Services Agreement, as amended, was for the period from 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 paid \$160,000 in management fees. At April 30, 2020 and April 30, 2019, \$58,333 and \$75,000, respectively, was included within related party payable on our balance sheet. The Master Services Agreement expired as of December 31, 2018.

On June 28, 2017, MCKEA and Spartan Capital Securities, LLC ("Spartan") entered into a five-year consulting agreement (the "McKEA Consulting Agreement"). Pursuant to the McKEA Consulting Agreement, upon the receipt by 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 our 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 our 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, we entered into a note receivable agreement with Avalanche in the amount of \$995,500, subject to the terms and conditions stated in the AVL P Note. The AVL P Note accrued interest at 10% per annum and included a 10% original issue discount. The balance outstanding on the AVL P Note as of April 30, 2020 was \$100,915. In August 2020, the principal and accrued interest on the AVL P Note was paid in full.

On April 30, 2019, we entered into a securities purchase agreement with Ault Life Science Fund ("ALSF") for the sale of 10,000,000 shares of our common stock, plus 5,000,000 warrants with a five-year term 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 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, our Executive Chairman.

The note is secured by a pledge of the purchased shares. While the securities purchase agreement provides for ALSF's ability to pledge the securities acquired thereby, given that the purchased securities are subject to the securities purchase agreement, we and ALSF agreed 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.

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Pursuant to the securities purchase agreement, ALSF is entitled to full ratchet anti-dilution protection, most-favored nation status, denying our company the right to enter into a variable rate transaction absent its consent, and the right to participate in any future financing we 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 our 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 III clinical trial. For purposes of the securities purchase agreement, 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 securities purchase agreement entitles ALSF the right to have all the shares of our common stock to which it is entitled under the securities purchase agreement be registered under the Securities Act within 180 days of the final closing of an initial public offering.

We agreed to enter into the securities purchase agreement with ALSF primarily as a result of the provision in the placement agent agreement related to the 2019 PPM that required us to provide anti-dilution protection to the placement agent, certain of its related parties and the investors in the private placement but not our other shareholders in the event that MCKEA were to convert its series A convertible preferred stock into common stock. ALSF and MCKEA are related parties, so we believe that it was fair and reasonable to permit ALSF to acquire shares of our 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 convertible preferred stock as our other shareholders would be harmed to some degree if MCKEA were to convert its series A convertible preferred stock.

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

In December 2018, we entered into a consulting agreement with William B. Horne, a director, 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.

In December 2020, DPW Holdings, Inc., a related party, provided \$1,000,000 in short-term advances.

In August 2020, we entered into a securities purchase agreement with DPW Holdings, Inc., a related party, to sell a convertible promissory note in the aggregate principal amount of \$50,000 and issue a 5-year warrant to purchase 16,667 of shares of our common stock. The convertible promissory note bears interest at 8% per annum, which principal and all accrued and unpaid interest are due six months after the date of issuance. The principal and interest earned on the convertible promissory note may be converted into shares of our common stock at \$1.50 per share. The exercise price of the warrant is \$3.00 per share.

Future Transactions

In connection with this offering, our Board of Directors has adopted a policy whereby any future transactions between our company and any of our subsidiaries, affiliates, officers, directors, principal stockholders or any affiliates of the foregoing will be on terms no less favorable to us than could reasonably be obtained in "arm's length" transactions with independent third parties, and any such transactions will also be approved by a majority of our disinterested outside directors.

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PRINCIPAL STOCKHOLDERS

The following table shows the beneficial ownership of our common stock as of December 29, 2020, held by (i) each person known by us to be the beneficial owner of more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our executive officers, and (iv) all of our directors and executive officers as a group. As of December 29, 2020, there were 64,762,858 shares of our common stock issued and outstanding and 750,000 shares of series A convertible preferred stock issued and outstanding, which will be converted into 15,000,000 shares of our common stock effective upon the closing of this offering.

Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power and/or investment power with respect to the securities held. Shares of our common stock subject to options and warrants currently exercisable or which may become exercisable within 60 days of the date of this prospectus, 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 our common stock shown as beneficially owned by them.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to their beneficially owned common stock.

Unless otherwise indicated, the principal address of each of the persons below is c/o Alzamend Neuro, Inc., 3802 Spectrum Blvd., Suite 112C, Tampa, Florida 33612.

Name of Beneficial Owner	Shares Beneficially Owned Before the Offering		Shares Beneficially Owned After the Offering	
	Shares	Percentage	Shares	Percentage
5% Stockholders:				
Ault Life Sciences, Inc. ⁽¹⁾	37,500,000	36.7%	37,500,000	
Ault Life Sciences Fund, LLC ⁽²⁾		21.5%	15,000,000	
Spartan Capital Securities, LLC ⁽³⁾	5,338,272	8.2%	5,338,272	
Directors and Executive Officers:				
Milton C. (Todd) Ault, III ⁽¹⁾⁽²⁾⁽⁴⁾	55,000,00	50.1%	55,000,000	
Stephan Jackman ⁽⁵⁾	1,687,500	2.5%	1,687,500	
Henry C.W. Nisser ⁽⁵⁾	546,875	*	546,875	
Kenneth S. Cragun ⁽⁵⁾	812,500	1.2%	812,500	
David Katzoff ⁽⁶⁾	579,083	*	579,083	
William B. Horne ⁽⁷⁾	2,578,125	3.8%	2,500,000	
Philip E. Mansour ⁽⁸⁾	2,500,000	3.7%	2,500,000	
All directors and executive officers as a group (7 persons)	63,125,000	53.3%	62,354,167	

* Less than one percent of outstanding shares.

(1) Includes 750,000 shares of series A convertible preferred stock that are convertible into 15,000,000 shares of our common stock effective upon the closing of this offering. Mr. Ault, our Executive Chairman, has sole voting and investment power with respect to the shares held by Ault Life Sciences, Inc.

(2) Includes 10,000,000 shares of our common stock and warrants to purchase 5,000,000 shares of our common stock. Mr. Ault, our Executive Chairman, has sole voting and investment power with respect to the shares and warrants held by Ault Life Sciences Fund, LLC.

(3) Includes 175,772 shares underlying warrants to purchase common stock, which are currently exercisable.

- (4) Includes stock options to purchase 2,500,000 shares of our common stock, which are currently exercisable.

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- (5) Consists of stock options to purchase shares of our common stock, which are currently exercisable. Mr. Nisser's address is 100 Park Avenue, Suite 1658, New York, NY 10017.
- (6) Consists of 18,000 shares of our common stock, 9,000 shares of common stock underlying a presently exercisable warrant and options to purchase shares of our common stock that are exercisable within 60 days of this prospectus.
- (7) Consists of stock options to purchase 2,578,125 shares of our common stock, which are currently exercisable.
- (8) Consists of stock options to purchase 2,500,000 shares of our common stock, which are currently exercisable.

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DESCRIPTION OF CAPITAL STOCK

The following is a description of our capital stock and the material provisions of our certificate of incorporation, bylaws and other agreements to which we and our stockholders are parties, in each case upon the closing of this offering.

General

Our authorized capital stock consists of 300,000,000 shares of common stock, par value \$0.001 per share. As of December 29, 2020, there were 64,762,858 shares of our common stock issued and outstanding held of record by 357 stockholders. After giving effect to the closing of this offering, our authorized capital stock will consist of an aggregate of 300,000,000 shares of common stock, of which _____ shares of common stock will be issued and outstanding immediately after the closing of this offering. Each such outstanding share of our common stock will be validly issued, fully paid and non-assessable.

A description of the material terms and provisions of our certificate of incorporation that will be in effect at the closing of our initial public offering and affecting the rights of holders of our capital stock is set forth below. The description is intended as a summary only.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each outstanding share of common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. Stockholders are not entitled to vote cumulatively for the election of directors. Except for the election of directors, which are elected by a plurality vote, a majority vote of common stockholders is generally required to take action under our certificate of incorporation and bylaws.

Conversion, Redemption and Preemptive Rights. Holders of our common stock have no conversion, redemption, preemptive, subscription or similar rights.

Preferred Stock

Immediately prior to the date of this prospectus, we were authorized to issue up to 10,000,000 shares of preferred stock, of which 750,000 shares of series A convertible preferred stock were outstanding. Effective upon the closing of this offering, the series A convertible preferred stock will be converted into shares of our common stock and retired, and we will be authorized to issue 10,000,000 shares of "blank-check" preferred stock. The Board of Directors will have the authority to issue this preferred stock in one or more series and to fix the number of shares and the relative rights, conversion rights, voting rights and terms of redemption (including sinking fund provisions) and liquidation preferences, without further vote or action by the stockholders. If shares of preferred stock with voting rights are issued, such issuance could affect the voting rights of the holders of our common stock by increasing the number of outstanding shares having voting rights, and by the creation of class or series voting rights. If the Board of Directors authorized the issuance of shares of preferred stock with conversion rights, the number of shares of common stock outstanding could potentially be increased by up to the authorized amount. Issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control of our company and may adversely affect the rights of the holders of our common stock. Also, preferred stock could have preferences over our common stock (and other series of preferred stock) with respect to dividend and liquidation rights. We currently have no plans to issue any preferred stock.

Warrants

In conjunction with a private offering of securities between June 2019 and October 2019, we issued 878,358 warrants with an exercise price of \$3.00 per share. In addition, we issued to the placement agent of the private offering warrants to purchase 175,672 shares of common stock (the "Placement Agent Warrants"), a figure equal to 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.

In March 2019, we 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 our company. The warrants vest over five years.

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On August 11, 2020, we issued warrants to purchase an aggregate of 91,667 shares of common stock at an exercise price equal to \$3.00 per share of common stock in connection with the issuance of a convertible promissory note in the principal amount of \$275,000.

On August 31, 2020, we issued warrants to purchase an aggregate of 16,667 shares of common stock at an exercise price equal to \$3.00 per share of common stock in connection with the issuance of a convertible promissory note, related party in the principal amount of \$50,000.

We have agreed to sell to the underwriters, for nominal consideration, warrants to purchase _____ shares of our common stock as additional consideration to the underwriters in this offering. In addition, we have granted the underwriters "piggyback" registration rights with respect to the underlying shares. This piggyback registration right will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(G)(v). See "Underwriting."

Limitations on Directors' Liability; Indemnification of Directors and Officers

As permitted by Delaware law, our certificate of incorporation provides that no director will be liable to us or our stockholders for monetary damages for breach of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of certain fiduciary duties as a director, except that a director will be personally liable for:

- any breach of his or her duty of loyalty to us or our stockholders;
- acts or omissions not in good faith which involve intentional misconduct or a knowing violation of law;
- the payment of dividends or the redemption or purchase of stock in violation of Delaware law; or
- any transaction from which the director derived an improper personal benefit.

This provision does not affect a director's liability under the federal securities laws.

At present, we do not maintain directors' and officers' liability insurance in order to limit the exposure to liability for indemnification of directors and officers, including liabilities under the Securities Act; however, we are in the process of obtaining such insurance.

Provisions of Our Certificate of Incorporation that May Have an Anti-Takeover Effect

Other than our authorized but unissued "blank-check" preferred stock available for future issuance without stockholder approval, as described under "Preferred Stock" above, our certificate of incorporation does not contain any provisions that may be deemed to have an anti-takeover effect or may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

Delaware Takeover Statute

In general, Section 203 of the Delaware General Corporation Law prohibits a Delaware corporation that is a public company from engaging in any "business combination" (as defined below) with any "interested stockholder" (defined generally as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with such entity or person) for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (3) on or subsequent to such date, the business combination is approved by the Board of Directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 of the Delaware General Corporation Law defines "business combination" to include: (1) any merger or consolidation involving the corporation and the interested stockholder; (2) any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder; (3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; (4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or (5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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Potential for Anti-Takeover Effects

While certain provisions of Delaware law may have an anti-takeover effect, these provisions are intended to enhance the likelihood of continuity and stability in the composition of our Board of Directors and in the policies formulated by the board, and to discourage certain types of transactions that may involve an actual or threatened change of control. In that regard, these provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our common stock that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management.

Choice of Forum

Our bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our bylaws will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Stock Exchange Listing

We have applied to have our common stock approved for trading on the NYSE American under the symbol ALZA.

Transfer Agent and Registrar

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have outstanding an aggregate of _____ shares of our common stock, representing approximately ____% of the shares of our common stock outstanding, and _____ shares of our common stock representing approximately ____% of the shares of our common stock outstanding if the underwriters exercise in full their option to purchase additional shares of our common stock. All of the shares of our common stock sold in this offering will be freely transferable without restriction or further registration under the Securities Act, subject to applicable securities laws, unless the shares of our common stock are owned by our “affiliates” as that term is defined in Rule 144 under the Securities Act.

The remaining _____ shares of our common stock have not been registered under the Securities Act. These securities are eligible for public sale in the United States only if they are registered under the Securities Act or if they qualify for an exemption from registration.

Lock-Up Agreements

We and each of our directors, executive officers and large institutional investors have agreed that, without the prior written consent of the representative on behalf of the underwriters, we and they will not, directly or indirectly, subject to limited exceptions that are described in “Underwriting” below, during the period ending 180 days after the date of this prospectus:

- issue, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock or publicly disclose the intention to do any of the foregoing;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the shares of our common stock;
- issue, offer, sell, agree to issue, offer or sell, solicit offers to purchase, grant any call option, warrant or other right to purchase, purchase any put option or other right to sell, pledge, borrow or otherwise dispose of the Shares or any securities convertible into or exercisable or exchangeable for the shares of our common stock (each a “**Relevant Security**”), or publicly disclose the intention to do any of the foregoing Relevant Security, or make any public announcement of any of the foregoing;
- establish or increase any “put equivalent position” or liquidate or decrease any “call equivalent position” (in each case within the meaning of Section 16 of the Exchange Act and the Rules and Regulations) with respect to any Relevant Security; or
- otherwise enter into any swap, derivative or other transaction or arrangement that transfers to another, in whole or in part, any economic consequence of ownership of a Relevant Security, whether or not such transaction is to be settled by delivery of Relevant Securities, other securities, cash or other consideration.

We will not file a registration statement under the Securities Act in connection with any transaction by us or any person that is prohibited pursuant to the foregoing.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement between us and the underwriters named below, for which _____ is acting as the representative (the “Representative”), we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, the number of shares of our common stock listed next to its name in the following table:

Underwriter	Number of Shares
Total	

Under the terms of the underwriting agreement, the underwriters are committed to purchase all of the shares offered by this prospectus (other than the shares subject to the underwriters’ option to purchase additional shares), if the underwriters buy any of such shares. The underwriters’ obligation to purchase the shares is subject to satisfaction of certain conditions, including, among others, the continued accuracy of representations and warranties made by us in the underwriting agreement, delivery of legal opinions and the absence of any material changes in our assets, business or prospects after the date of this prospectus.

The underwriters initially propose to offer the common stock directly to the public at the public offering price set forth on the front cover page of this prospectus and to certain dealers at such offering price less a concession not to exceed \$_____ per share. After the initial public offering of the shares of our common stock, the offering price and other selling terms may be changed by the underwriters. Sales of shares of our common stock made outside the United States may be made by affiliates of certain of the underwriters.

Over-Allotment Option

We have granted to the underwriters an option to purchase up to _____ additional shares of our common stock at the same price per share as they are paying for the shares shown in the table above. The underwriters may exercise this option in whole or in part at any time within 30 days after the date of the underwriting agreement. To the extent the underwriters exercise this option, each underwriter will be committed, so long as the conditions of the underwriting agreement are satisfied, to purchase a number of additional shares proportionate to that underwriters’ initial commitment as indicated in the table at the beginning of this section plus, in the event that any underwriter defaults in its obligation to purchase shares under the underwriting agreement, certain additional shares.

Discounts and Commissions

The following table shows the per share and total underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of our common stock.

	Per Share	No Exercise	Total Full Exercise
Public offering price	\$	\$	\$
Underwriting discount to be paid by us	\$	\$	\$
Total	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

We estimate that the total expenses of the offering payable by us, excluding underwriting discount, will be approximately \$ _____. We have agreed to reimburse the underwriters for certain of their expenses, including fees of counsel in connection with filing with FINRA, in an amount not to exceed \$ _____.

Stabilization

In accordance with Regulation M under the Exchange Act, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock, including short sales and purchases to cover positions created by short positions, stabilizing transactions, syndicate covering transactions, penalty bids and passive market making.

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- Short positions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares or purchasing shares in the open market.
- Stabilizing transactions permit bids to purchase the underlying security as long as the stabilizing bids do not exceed a specific maximum price.
- Syndicate covering transactions involve purchases of our common stock in the open market after the distribution has been completed to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the underwriters' option to purchase additional shares. If the underwriters sell more shares than could be covered by the underwriters' option to purchase additional shares, thereby creating a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.
- In passive market making, market makers in our common stock who are underwriters or prospective underwriters may, subject to limitations, make bids for or purchase shares of our common stock until the time, if any, at which a stabilizing bid is made.

These activities may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NYSE American or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the Representative will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Indemnification

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of such liabilities.

Discretionary Accounts

The underwriters have informed us that they do not expect to make sales to accounts over which they exercise discretionary authority in excess of 5% of the shares of our common stock being offered in this offering.

IPO Pricing

Prior to the completion of this offering, there has been no public market for our common stock. The initial public offering price has been negotiated between us and the Representative. Among the factors considered in these negotiations are: the history of, and prospects for, us and the industry in which we compete; our past and present financial performance; an assessment of our management; the present state of our development; the prospects for our future earnings; the prevailing conditions of the applicable United States securities market at the time of this offering; previous trading prices for our common stock in the private market and market valuations of publicly traded companies that we and the representative believe to be comparable to us.

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Lock-Up Agreements

We have agreed that for a period of 180 days after the date of the underwriting agreement, we will not, without the prior written consent of the Representative, which

may be withheld or delayed in the Representative's sole discretion:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, lend or otherwise dispose of or transfer, directly or indirectly, any of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, or file any registration statement under the Securities Act with respect to any of the foregoing; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of any of our common stock;

whether any such transaction described above is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise. The prior sentence will not apply to (i) the shares to be sold pursuant to the underwriting agreement, (ii) any shares of our common stock issued by us upon the exercise of an option or other security outstanding on the date hereof, (iii) such issuances of options or grants of restricted stock or other equity-based awards under our 2020 Stock Incentive Plan and the issuance of shares issuable upon exercise of any such equity-based awards, and (iv) the filing by us of registration statements on Form S-8.

Each of our directors and our executive officers has agreed that for a period ending 180 days after the date of the underwriting agreement, none of them will, without the prior written consent of the Representative which may be withheld or delayed in the Representative's sole discretion:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, lend or otherwise dispose of or transfer, directly or indirectly, any shares of our common stock, or any securities convertible into or exercisable or exchangeable for our common stock owned directly by such director or executive officer or with respect to which such director or executive officer has beneficial ownership; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock, whether any such transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

Notwithstanding the prior sentence, subject to applicable securities laws and the restrictions contained in our charter, our directors and executive officers may transfer our securities: (i) pursuant to the exercise or conversion of our securities, including, without limitation, options and warrants; (ii) as a bona fide gift or gifts, provided that the donee or donees thereof agree to be bound in writing by the restrictions set forth above; (iii) to any trust for the direct or indirect benefit of such director or executive officer or the immediate family of such director or executive officer, provided that the trustee of the trust agrees to be bound in writing by the restrictions set forth above; (iv) any transfer required under any benefit plans or our charter or bylaws; (v) as required by participants in our 2020 Stock Incentive Plan in order to reimburse or pay federal income tax and withholding obligations in connection with vesting of restricted stock grants or the exercise of stock options or warrants; or (vi) in or in connection with any merger, consolidation, combination or sale of all or substantially all of our assets or in connection with any tender offer or other offer to purchase at least 50% of our common stock.

Notwithstanding the foregoing, nothing will prevent our directors or executive officers from, or restrict their ability to, (i) purchase our securities in a public or private transaction, or (ii) exercise or convert any options, warrants or other convertible securities issued to or held by such director or executive officer, including those granted under our 2020 Stock Incentive Plan.

Other Relationships

The Representative may in the future provide us and our affiliates with investment banking and financial advisory services for which it may in the future receive customary fees. The Representative may release, or authorize us to release, as the case may be, the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.

Electronic Distribution

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in the offering. The Representative may allocate a number of shares to the underwriters and selling group members, if any, for sale to their online brokerage account holders. Any such allocations for online distributions will be made by the representative on the same basis as other allocations.

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Listing

In connection with this offering, we intend to apply to have our common stock listed on the NYSE American under the symbol "ALZA." There is no assurance, however, that our common stock will be listed on the NYSE American or any other national securities exchange.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Selling Restrictions

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

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United Kingdom

Each underwriter has represented and agreed that:

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, or FSMA) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of shares.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or the ASIC, in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, the Exempt Investors, who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

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LEGAL MATTERS

Olshan Frome Wolosky LLP, New York, New York will pass upon the validity of the issuance of the shares of our common stock being offered by this prospectus as our counsel. Certain legal matters will be passed upon for the underwriters by _____.

EXPERTS

The financial statements of Alzamend Neuro, Inc. as of April 30, 2020 and 2019 and for each of the two years in the period ended April 30, 2020 included in this prospectus and in this registration statement have been audited by Squar Milner LLP (which effective as of November 1, 2020, merged with Baker Tilly US, LLP), an

independent registered public accounting firm, as stated in its report thereon (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the entity's ability to continue as a going concern), and included in this prospectus and registration statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including amendments and relevant exhibits and schedules, under the Securities Act covering the Securities to be sold in this offering. This prospectus, which constitutes a part of the registration statement, summarizes material provisions of contracts and other documents that we refer to in the prospectus. Since this prospectus does not contain all of the information contained in the registration statement, you should read the registration statement and its exhibits and schedules for further information with respect to us and the Securities. You may review and copy the registration statement, reports and other information we file at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. You may also request copies of these documents upon payment of a duplicating fee by writing to the SEC. For further information on the public reference facility, please call the SEC at 1-800-SEC-0330. Our SEC filings, including the registration statement, are also available to you on the SEC's Web site at <http://www.sec.gov>.

Immediately upon completion of this offering, we will become subject to periodic reporting and other informational requirements of the Securities Exchange Act of 1934 and will file annual, quarterly and current reports, proxy statements and other information with the SEC. We maintain a website at <http://www.alzamend.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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ALZAMEND NEURO, INC. Balance Sheets

	<u>October 31, 2020</u> <u>(unaudited)</u>	<u>April 30, 2020</u>
ASSETS		
CURRENT ASSETS		
Cash	\$ 5,860	\$ 90,285
Note receivable, related party, net	-	100,915
Prepaid expenses and other current assets	976,067	1,622,815
TOTAL CURRENT ASSETS	<u>981,927</u>	<u>1,814,015</u>
TOTAL ASSETS	<u>\$ 981,927</u>	<u>\$ 1,814,015</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 1,265,747	\$ 929,639
Related party payable	63,335	62,667
Note payable	62,110	-

Convertible notes, net	216,983	-
Convertible notes, related party, net	40,519	-
TOTAL CURRENT LIABILITIES	1,648,694	992,306
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
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 October 31, 2020 and April 30, 2020, respectively	75	75
Common stock, \$0.0001 par value: 300,000,000 shares authorized; 64,762,858 shares issued and outstanding as of October 31, 2020 and April 30, 2020, respectively	6,476	6,476
Additional paid-in capital	28,666,695	27,584,227
Note receivable for common stock – related party	(14,883,295)	(14,983,200)
Accumulated deficit	(14,456,718)	(11,785,869)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(666,767)	821,709
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 981,927	\$ 1,814,015

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

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ALZAMEND NEURO, INC.
Statements of Operations
(unaudited)

	For the Six Months Ended October 31,	
	2020	2019
OPERATING EXPENSES		
Research and development	\$ 783,759	\$ 399,916
General and administrative	1,832,494	1,491,825
Total operating expenses	2,616,253	1,891,741
Loss from operations	(2,616,253)	(1,891,741)
OTHER INCOME (EXPENSE), NET		
Interest expense	(50,815)	-
Interest expense - related party	(5,487)	-
Interest income - related party	1,706	8,893
Total other income (expense), net	(54,596)	8,893
NET LOSS	\$ (2,670,849)	\$ (1,882,848)
Basic and diluted net loss per common share	\$ (0.04)	\$ (0.03)
Basic and diluted weighted average common shares outstanding	72,262,858	70,913,449

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

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ALZAMEND NEURO, INC.
Statements of Cash Flows
(unaudited)

	For the Six Months Ended October 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (2,670,849)	\$ (1,882,848)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest expense - debt discount	45,625	-
Interest expense - debt discount, related party	4,819	-
Stock-based compensation to employees and consultants	1,160,370	1,056,383
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	475,904	(356,444)
Accounts payable and accrued expenses	336,108	(600,687)
Related party payable	-	1,834
Net cash used in operating activities	(648,023)	(1,781,762)
Cash flows from investing activities:		
Proceeds from repayments of notes receivable - related party	100,915	105,000
Net cash provided by investing activities	100,915	105,000

Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants, net	-	1,799,773
Advances from related party payable	668	-
Proceeds from note payable	62,110	-
Proceeds from note receivable for common stock – related party	99,905	-
Proceeds from convertible note payable	250,000	-
Proceeds from convertible note payable, related party	50,000	-
Net cash provided by financing activities	462,683	1,799,773
Net (decrease) increase in cash	(84,425)	123,011
Cash at beginning of period	90,285	42,606
Cash at end of period	\$ 5,860	\$ 165,617
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
Issuance of common stock for subscription receivable	\$ -	\$ 481,554
Issuance of common stock for prepaid consulting services	\$ -	\$ 683,379
Fair value of warrants issued in connection with convertible notes payable	\$ 92,942	\$ -

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

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ALZAMEND NEURO, INC.
Statements of Changes in Stockholders' Equity (Deficit)
Six Months Ended October 31, 2020
(unaudited)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable for Common Stock - Related Party	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
BALANCES, April 30, 2020	750,000	\$ 75	64,762,858	\$ 6,476	\$ 27,584,227	\$ (14,983,200)	\$ (11,785,869)	\$ 821,709
Stock-based compensation to employees and consultants	-	-	-	-	989,526	-	-	989,526
Proceeds from note receivable – related party for common stock	-	-	-	-	-	99,905	-	99,905
Fair value of warrants issued in connection with convertible notes	-	-	-	-	78,642	-	-	78,642
Fair value of warrants issued in connection with convertible notes - related party	-	-	-	-	14,300	-	-	14,300
Net loss	-	-	-	-	-	-	(2,670,849)	(2,670,849)
BALANCES, October 31, 2020	750,000	\$ 75	64,762,858	\$ 6,476	\$ 28,666,695	\$ (14,883,295)	\$ (14,456,718)	\$ (666,767)

ALZAMEND NEURO, INC.
Statements of Changes in Stockholders' Equity
Six Months Ended October 31, 2019
(unaudited)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable for Common Stock - Related Party	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
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	-	-	2,284,393	228	2,288,107	-	-	2,288,335
Stock-based compensation to employees and consultants	-	-	-	-	829,534	-	-	829,534
Issuance of common stock for services	-	-	500,000	50	658,329	-	-	658,379
Net loss	-	-	-	-	-	-	(1,882,848)	(1,882,848)
BALANCES, October 31, 2019	750,000	\$ 75	64,662,858	\$ 6,466	\$ 26,462,255	\$ (15,000,000)	\$ (9,258,481)	\$ 2,210,315

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

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ALZAMEND NEURO, INC.
NOTES TO FINANCIAL STATEMENTS — Unaudited

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”).

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 financial statements have been prepared on the basis that the Company will continue as a going concern. As of October 31, 2020, the Company had cash of \$5,860 and an accumulated deficit of \$14,456,718. The Company has incurred recurring losses for the six months ended October 31, 2020 totaling \$2,670,849. In the past, the Company has financed its operations principally through issuances of promissory notes and equity securities.

The Company expects to continue to incur losses for the foreseeable future and needs to raise additional capital until it is able to generate revenues from operations sufficient to fund its development and commercial operations. Based on our current business plan, we believe that our cash and cash equivalents at October 31, 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 Semiannual Report on Form 1-SA. 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.

Impact of Coronavirus on the Company’s Operations

In March 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic which continues to spread throughout the United States and the world. We are monitoring the outbreak of COVID-19 and the related business and travel restrictions and changes to behavior intended to reduce its spread, and its impact on our operations, financial position, cash flows, supply chains, and the industry in general, in addition to the impact on our employees. Due to the rapid development and fluidity of this situation, the magnitude and duration of the pandemic and its impact on our operations and liquidity is uncertain as of the date of this semiannual report.

The outbreak of COVID-19 could adversely impact our business, including delaying our nonclinical studies and clinical trials. We are still assessing our business operations and system supports and the impact COVID-19 may have on our results of operations and financial condition, but there can be no assurance that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular.

Our operations are located in Orange County, CA and Tampa, FL, and members of our senior management work in Atlanta, GA and New York, NY. We have been following the recommendations of local health authorities to minimize exposure risk for our employees, including the temporary closures of our offices and having employees work remotely to the extent possible, which has to an extent adversely affected their efficiency.

Our offices remain closed to non-essential employees based on the occupancy and social distancing orders from health authorities. Non-essential staff continue to work remotely utilizing secure remote access systems and technology infrastructure. The Company believes it has adequate internal communications system and can remain operational with a remote staff.

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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 applicable rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. In management’s opinion, the accompanying statements reflect adjustments necessary to present fairly the financial position, results of operations, and cash flows for those periods indicated, and contain adequate disclosure to make the information presented not misleading. Adjustments included herein are of a normal, recurring nature unless otherwise disclosed in the footnotes. The financial statements and notes thereto should be read in conjunction with the Company’s audited financial statements and notes thereto for the year ended April 30, 2020 included in the Company’s Annual Report on Form 1-K, as filed with the SEC on August 28, 2020. The accompanying balance sheet at October 31, 2020 has been derived from the audited balance sheet at April 30, 2020 contained in the above referenced Form 1-K. Results of operations for interim periods are not necessarily indicative of the results of operations for a full year.

Effective June 28, 2018, the board of directors approved a 1-for-4 reverse stock split of our Common Stock. 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 our 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 June 28, 2018. All historical share and per-share amounts reflected throughout the financial statements and other financial information in this filing have been adjusted to reflect the reverse stock split. The par value per share of our Common Stock was not affected by the reverse stock split.

Accounting Estimates

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less when purchased to be cash equivalents. As of October 31, 2020

and April 30, 2020, the Company had no cash equivalents.

Fair Value of Financial Instruments

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

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.

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The fair values of warrants are determined using the Black-Scholes valuation model, a "Level 3" fair value measurement, based on the estimated fair value of common stock, volatility based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities, the expected life based on the remaining contractual term of the conversion option and warrants and the risk free interest rate based on the implied yield available on U.S. Treasury Securities with a maturity equivalent to the warrants' contractual life.

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. As of October 31, 2020, the Company has fully reserved the net deferred income tax assets by taking a full valuation allowance against these assets.

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 October 31, 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.

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.

Stock-Based Compensation

The Company accounts for stock option awards in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic No. 718, *Compensation-Stock Compensation*. Under 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.

Warrants

The Company accounts for stock warrants as either equity instruments, derivative liabilities, or liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*, depending on the specific terms of the warrant agreement.

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Debt Issued with Warrants

The Company considers guidance within ASC 470-20, *Debt*, ASC 480, and ASC 815 when accounting for the issuance of convertible debt with detachable warrants.

As described above under the caption “Warrants,” the Company classifies stock warrants as either equity instruments, derivative liabilities, or liabilities depending on the specific terms of the warrant agreement.

In circumstances in which debt is issued with equity-classified warrants, the proceeds from the issuance of convertible debt are allocated to the warrants and convertible debt based on their relative estimated fair value. The fair value of equity warrants is recorded as a discount to the convertible debt with a corresponding increase to additional paid-in capital. The debt discount and amortized as interest expense using effective interest method.

Embedded Derivatives. The Company considers whether there are any embedded features in debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC 815.

Beneficial Conversion Feature. If the amount allocated to the convertible debt results in an effective per share conversion price less than the fair value of the Company’s common stock on the commitment date, the intrinsic value of this beneficial conversion feature is recorded as a discount to the convertible debt with a corresponding increase to additional paid-in capital. The beneficial conversion feature discount is equal to the difference between the effective conversion price and the fair value of the Company’s common stock at the commitment date, unless limited by the remaining proceeds allocated to the debt. At issuance, the effective conversion price of the Company’s convertible notes payable were not deemed to be below estimated fair value of the Company’s common stock, and as a result, no beneficial conversion feature was recorded.

The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from allocation of proceeds to interest expense using the effective interest method over the expected term of the Notes pursuant to ASC 835, *Interest*.

Loss per Common Share

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

Since the effects of outstanding options, warrants and convertible preferred stock are anti-dilutive in the periods 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, warrants, and convertible notes that have been exclude from the computation of loss per common share:

	For the Six Months Ended October 31,	
	2020	2019
Series A convertible preferred stock	15,000,000	15,000,000
Stock options (1)	16,300,000	9,975,000
Warrants	6,760,469	6,652,035
Convertible notes	216,666	-
	<u>38,277,135</u>	<u>31,627,035</u>

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

Reclassifications

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

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) 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 are not expected to 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.

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.

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40)*. This ASU reduces the number of accounting models for convertible debt instruments and convertible preferred stock. As well as amend the guidance for the derivatives scope exception for contracts in an entity’s own equity to reduce form-over-substance-based accounting conclusions. In addition, this ASU improves and amends the related EPS guidance. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods therein. Adoption is either a modified retrospective method or a fully retrospective method of transition. We are currently assessing the impact the new guidance will have on our financial statements.

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.

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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. 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 accounted for the AVLP Note at amortized cost, which represented the amount at which the promissory note was acquired, adjusted for accrued interest and accretion of original issue discount. Interest was accreted using the effective interest method. The Company recorded interest on an accrual basis and recognized 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 six months ended October 31, 2020, the Company recorded contractual interest income from the stated interest rate of \$1,706.

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, 2021. 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. During the six months ended October 31, 2020, proceeds from the note receivable for common stock, related party, were \$99,905.

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are as follows:

	October 31, 2020	April 30, 2020
Prepaid consulting fees	\$ 959,007	\$ 1,513,602
Interest receivable	-	77,153
Other prepaid expenses	850	15,850
Other receivables	16,210	16,210
Total prepaid expenses and other current assets	\$ 976,067	\$ 1,622,815

6. 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.

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A summary of stock option activity for the period April 30, 2020 to October 31, 2020, is presented below:

		Outstanding Options		
Shares Available for	Number of	Weighted Average Exercise	Weighted Average Remaining Contractual	Aggregate Intrinsic

	Grant	Options	Price	Life (years)	Value
Balance at April 30, 2020	575,000	19,425,000	\$ 0.5228	6.89	\$ 15,609,500
Options granted	(125,000)	125,000	\$ 1.4267		
Balance at October 31, 2020	450,000	19,550,000	\$ 0.6964	6.41	\$ 15,609,500
Options vested and expected to vest at October 31, 2020		17,425,000	\$ 0.6616	6.97	\$ 14,609,500
Options exercisable at October 31, 2020		10,424,452	\$ 0.3053	6.31	\$ 12,880,578

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (i.e., the difference between the estimated fair value price on the respective date and the exercise price, times the number of shares) that would have been received by the option holders had all option holders exercised their options. There have not been any options exercised during the six months ended October 31, 2020.

Stock options granted to employees and consultants

The estimated fair value of stock options granted to employees and consultants during the six months ended October 31, 2020 and 2019, were calculated using the Black-Scholes option-pricing model using the following assumptions:

	For the Six Months Ended October 31,	
	2020	2019
Expected term (in years)	6.25	5.20
Volatility	100.1%	70.0%
Risk-free interest rate	0.51%	2.25%
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.

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Stock-based compensation to employees and consultants from stock option grants for the six months ended October 31, 2020 and 2019 was \$989,526 and \$829,534, respectively.

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 October 31, 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 October 31, 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, defined 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 10, 2019 date of issuance. The stock compensation expense is being recognized over the two-year term of the agreement. During the six months ended October 31, 2020, the Company recognized stock compensation expense of \$170,844 related to the Uplisting 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-based compensation expense

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

For the Six Months Ended October 31,

	2020	2019
Research and development	\$ 43,626	\$ 115,873
General and administrative	1,116,744	940,510
Total	<u>\$ 1,160,370</u>	<u>\$ 1,056,383</u>

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As of October 31, 2020, total unamortized stock-based compensation expense related to unvested employee and non-employee awards that are expected to vest was \$4.6 million. The weighted-average period over which such stock-based compensation expense will be recognized is approximately 2.4 years.

7. WARRANTS

During the six months ended October 31, 2020, the Company issued warrants to purchase an aggregate of 108,334 shares of common stock at an exercise price of \$3.00 per share.

On August 11, 2020, the Company issued warrants to purchase an aggregate of 91,667 shares of common stock at an exercise price equal to \$3.00 per share of common stock in connection with the issuance of a convertible promissory note in the principal amount of \$275,000 (see Note 8). Based on the terms of the Company's warrant agreement, the Company accounted for the warrants as equity instruments as the warrants are indexed to the Company's own stock, require settlement in shares and would be classified as equity under ASC 815.

On August 31, 2020, the Company issued warrants to purchase an aggregate of 16,667 shares of common stock at an exercise price equal to \$3.00 per share of common stock in connection with the issuance of a convertible promissory note, related party in the principal amount of \$50,000 (see Note 9). Based on the terms of the Company's warrant agreement, the Company accounted for the warrants as equity instruments as the warrants are indexed to the Company's own stock, require settlement in shares and would be classified as equity under ASC 815.

The following table summarizes information about Common Stock warrants outstanding at October 31, 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	3.3	\$ 1.00	158,333	\$ 1.00
\$1.20	5,500	-0.2	\$ 1.20	5,805	\$ 1.20
\$1.75	175,772	4.0	\$ 1.75	35,154	\$ 1.75
\$3.00	6,079,197	3.4	\$ 3.00	1,730,141	\$ 3.00
<u>\$1.00 - \$3.00</u>	<u>6,760,469</u>	<u>3.8</u>	<u>\$ 2.82</u>	<u>1,929,433</u>	<u>\$ 2.81</u>

The estimated fair value of warrants granted during the six months ended October 31, 2020 and 2019, were calculated using the Black-Scholes option-pricing model using the following assumptions:

	For the Six Months Ended October 31,	
	2020	2019
Expected term (in years)	5.00	2.50
Volatility	103.70%	69.35%
Risk-free interest rate	0.27% - 0.28%	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.

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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.

8. OTHER RELATED PARTY TRANSACTIONS

In December 2018, we entered into a consulting agreement with Mr. William Horne, one of the Company's directors, 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.

9. CONVERTIBLE NOTE

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.

The fair value of equity warrants was recorded as a discount to the convertible promissory note with a corresponding increase to additional paid-in capital. The Company computed the estimated fair value of the warrants using the Black-Scholes option pricing model and, as a result of this calculation, recorded debt discount in the amount of \$78,642 based on the estimated fair value of the warrants. The risk-free rate of 0.27% was derived from the U.S. Treasury yield curve, matching the term of the warrant, in effect at the measurement date. The volatility factor of 103.7% was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. In aggregate, the Company recorded debt discount in the amount of \$103,642 based on the fair values of the warrants and original issue discount of \$25,000. As of October 31, 2020, the convertible note is presented net of unamortized debt discount of \$58,017.

10. NOTE PAYABLE

In May 2020, the Company received loan proceeds in the amount of \$62,110 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after the earlier of (i) 24 weeks after the loan disbursement date and (ii) December 31, 2020 as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels.

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP. In December 2020, the Company met the conditions and received forgiveness of the loan.

11. CONVERTIBLE NOTE – RELATED PARTY

In August 2020, the Company entered into a Securities Purchase Agreement with DPW Holdings, Inc., a related party, to sell a Convertible Promissory Note of the Company, in the aggregate principal amount of \$50,000 and issue a 5-year warrant to purchase 16,667 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.

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The fair value of equity warrants was recorded as a discount to the convertible promissory note with a corresponding increase to additional paid-in capital. The Company computed the estimated fair value of the warrants using the Black-Scholes option pricing model and, as a result of this calculation, recorded debt discount in the amount of \$14,300 based on the estimated fair value of the warrants. The risk-free rate of 0.28% was derived from the U.S. Treasury yield curve, matching the term of the warrant, in effect at the measurement date. The volatility factor of 103.7% was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. As of October 31, 2020, the convertible note – related party is presented net of unamortized debt discount of \$9,481.

12. EQUITY TRANSACTIONS

The Company is authorized to issue 10,000,000 shares of Preferred Stock \$0.0001 par value. The Board of Directors has designated 1,360,000 shares as Series A Convertible Preferred Stock (the "Series A Preferred Shares"). The rights, preferences, privileges and restrictions on the remaining authorized 8,640,000 shares of Preferred Stock have not been determined. The Company's Board of Directors is authorized to create a new series of preferred shares and determine the number of shares, as well as the rights, preferences, privileges and restrictions granted to or imposed upon any series of preferred shares. As of October 31, 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:

- 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.

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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.

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.

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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.

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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.

13. SUBSEQUENT EVENTS

In accordance with FASB ASC 855-10, the Company has analyzed its operations subsequent to October 31, 2020 and has determined that it does not have any material subsequent events to disclose in these financial statements except for the following:

In December 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 \$44,000 for a purchase price of \$40,000 and issue a 5-year warrant to purchase 14,667 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.

In December 2020, DPW Holdings, Inc., a related party, provided \$1,000,000 in short-term advances.

In December 2020, the Company met the conditions and received forgiveness of the \$62,110 note payable under the PPP established as part of the CARES Act.

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REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Alzamend Neuro, Inc. (the Company) as of April 30, 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

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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	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.

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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.

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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	562,277	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(124,317)	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	<u>\$ 90,285</u>	<u>\$ 42,606</u>
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
Issuance of common stock for note receivable – related party	\$ -	\$ 15,000,000
Issuance of common stock for prepaid consulting services	\$ 683,379	\$ -

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

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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 Capital	Note Receivable for Common Stock - Related Party	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
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	<u>750,000</u>	<u>\$ 75</u>	<u>64,762,858</u>	<u>\$ 6,476</u>	<u>\$ 27,584,227</u>	<u>\$ (14,983,200)</u>	<u>\$ (11,785,869)</u>	<u>\$ 821,709</u>

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

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ALZAMEND NEURO, INC.
NOTES TO FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Alzamend Neuro, Inc. (the “Company” or “Alzamend”), is a specialty pharmaceutical company that was formed on February 26, 2016, to develop and commercialize patented intellectual property to prevent, treat and cure Alzheimer’s disease (“Alzheimer’s” or “AD”). The Company has licensed an immunotherapy vaccine peptide that works both as a treatment and vaccine against Alzheimer’s and an ionic cocrystal of lithium to mitigate extreme agitation and forestall other deterioration as displayed by patients with up to moderate AD and possibly other neurodegenerative diseases (collectively, the “Technology”).

On June 28, 2018, the Company implemented a 1-for-4 Reverse Stock Split of its Common Stock. 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 June 28, 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").

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Accounting Estimates

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less when purchased to be cash equivalents. The recorded carrying amounts of the Company's cash and cash equivalents approximate their fair value. As of April 30, 2019 and 2018, the Company had no cash equivalents.

Fair Value of Financial Instruments

Our financial instruments are accounts payable. 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 50% 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.

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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, 2019 and 2018.

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
	<u>37,827,135</u>	<u>28,794,172</u>

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

Reclassifications

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

Recent Accounting Standards

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

In February 2016, the FASB issued No. 2016-02, *Leases* ("Topic 842" or "ASU 2016-02"), which supersedes the guidance in former ASC 840, *Leases*. The FASB issued further updates to this guidance in July 2018 through ASU 2018-10, *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Leases* (Topic 842): *Targeted Improvements*. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. The standard is effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted, and is required to be adopted using a modified retrospective approach. The Company 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.

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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:

	<u>April 30, 2020</u>	<u>April 30, 2019</u>
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	<u>\$ 1,622,815</u>	<u>\$ 1,252,396</u>

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.

	<u>April 30, 2020</u>	<u>April 30, 2019</u>
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	<u>\$ -</u>	<u>\$ -</u>

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

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

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.

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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:

	Shares Available for Grant	Number of Options	Outstanding 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 to the Chief Executive Officer. These options have an exercise price of \$1.00 per share.

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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	\$ 159,499	\$ 2,227,923
General and administrative	2,054,294	396,170
Total	<u>\$ 2,213,793</u>	<u>\$ 2,624,093</u>

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 \$5.4 million. The weighted-average period over which such stock-based compensation expense will be recognized is approximately 2.8 years.

8. WARRANTS

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

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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

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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, \$58,333 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.

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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.

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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.

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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.

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On July 2, 2018, the Company obtained two royalty-bearing, exclusive worldwide licenses from the Licensor to a therapy known as LiProSalTM to mitigate extreme agitation and forestall other deterioration as displayed by patients with up to moderate AD. LiProSalTM 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 LiProSalTM technology, pursuant to the terms of the Standard Exclusive License Agreements with Sublicensing Terms, both dated June 21, 2018, (the "LiProSalTM 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 LiProSalTM licenses, in the aggregate, the Company is required to pay initial license fees of \$50,000 no later than July 31, 2018, and \$150,000 no later than March 31, 2019. As an additional licensing fee, the Licensor is entitled to receive that number of shares of Common Stock equal to three percent (3%) of the sum of the total number of issued and outstanding shares. Additionally, the Company is required to pay milestone payments on the due dates to Licensor for

the license of the technology, as follows:

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.

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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 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.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses payable by us in connection with the issuance and distribution of the securities being registered hereunder. All of the amounts shown are estimates, except for the SEC Registration Fee.

SEC Registration Fee	\$
FINRA Filing Fee	
Initial NYSE American Listing Fee	
Printing Fees and Expenses	\$ *
Accounting Fees and Expenses	\$ *
Legal Fees and Expenses	\$ *
Transfer Agent and Registrar Fees	\$ *
Miscellaneous Fees and Expenses	\$ *
Total	\$ *

* To be completed by amendment.

ITEM 14. INDEMNIFICATION OF OFFICERS AND DIRECTORS

Section 145 of the Delaware General Corporation Law (the “DGCL”) empowers a Delaware corporation to indemnify any persons who are, or are threatened to be made, parties to any threatened, pending, or completed legal action, suit, or proceeding, whether civil, criminal, administrative, or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer or director of such corporation, or is or was serving at the request of such corporation as a director, officer, employee, or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys’ fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit, or proceeding, provided that such officer or director acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation’s best interests, and, for criminal proceedings, had no reasonable cause to believe his conduct was illegal. A Delaware corporation may indemnify officers and directors in an action by or in the right of the corporation under the same conditions, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation in the performance of his duty. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director actually and reasonably incurred.

Our bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law, except that no indemnification will be provided to a director, officer, employee, or agent if the indemnification sought is in connection with a proceeding initiated by such person without the authorization of our Board of Directors. The bylaws also provide that the right of directors and officers to indemnification will be a contract right and will not be exclusive of any other right now possessed or hereafter acquired under any statute, provision of the certificate of incorporation, bylaw, agreement, vote of stockholders or disinterested directors or otherwise. The bylaws also permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in such capacity, regardless of whether the bylaws would permit indemnification of any such liability.

In accordance with Section 102(b)(7) of the DGCL, our certificate of incorporation provides that directors will not be personally liable for monetary damages for breaches of their fiduciary duty as directors except for (i) breaches of their duty of loyalty to us or our stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or knowing violations of law, (iii) certain transactions under Section 174 of the DGCL (unlawful payment of dividends or unlawful stock purchases or redemptions), or (iv) transactions from which a director derives an improper personal benefit. The effect of this provision is to eliminate the personal liability of directors for monetary damages or actions involving a breach of their fiduciary duty of care, including any actions involving gross negligence.

In addition, we have entered into indemnification agreements with our directors and officers that require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service, so long as the indemnitee acted in good faith and in a manner the indemnitee reasonably believed to be in or not opposed to the best interests of our company and, with respect to any criminal action or proceeding, the indemnitee had no reasonable cause to believe his or her conduct was unlawful. We also maintain director and officer liability insurance to insure our directors and officers against the cost of defense, settlement or payment of a judgment under specified circumstances.

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Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

Sales of unregistered securities subsequent to April 30, 2020

In December 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 \$44,000 for a purchase price of \$40,000 and issue a 5-year warrant to purchase 14,667 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.

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.

In August 2020, the Company entered into a Securities Purchase Agreement with DPW Holdings, Inc., a related party, to sell a Convertible Promissory Note of the Company, in the aggregate principal amount of \$50,000 and issue a 5-year warrant to purchase 16,667 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 year ended April 30, 2020

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.

During the year ended April 30, 2019

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 initially with a 12-month term from Ault Life Sciences Fund, LLC, a related party. The term of the note receivable was extended to December 31, 2021. 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. During the six months ended October 31, 2020, proceeds from the note receivable for common stock, related party, were \$99,905.

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.

During the year ended April 30, 2018

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

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following exhibits are filed with this registration statement.

Exhibit No.	Exhibit Description
3.1	<u>Certificate of Incorporation (Incorporated by reference to Exhibit 2.1 of Form DOS filed with the Securities and Exchange Commission on August 19, 2016)</u>
3.2	<u>Bylaws (Incorporated by reference to Exhibit 2.2 of Form DOS filed with the Securities and Exchange Commission on August 19, 2016)</u>
3.3	<u>Certificate of Designation of Alzamend Neuro, Inc. Series A Convertible Preferred Stock, dated May 30, 2016 (Incorporated by reference to Exhibit 2.3 of Form 1-A/A filed with the Securities and Exchange Commission on February 4, 2020).</u>
4.1	<u>Promissory Note Due April 30, 2020, issued by Ault Life Sciences Fund, LLC, dated April 30, 2019 (Incorporated by reference to Exhibit 3.1 of Form 1-A/A filed with the Securities and Exchange Commission on February 4, 2020).</u>
4.2	<u>Amendment to Note Due April 30, 2020, by and between Ault Life Sciences Fund, LLC, and Alzamend Neuro, Inc., dated June 11, 2019 (Incorporated by reference to Exhibit 3.2 of Form 1-A/A filed with the Securities and Exchange Commission on February 4, 2020).</u>
4.3	<u>Warrant to Purchase Common Stock issued to Ault Life Sciences Fund, LLC, dated April 30, 2019 (Incorporated by reference to Exhibit 3.3 of Form 1-A/A filed with the Securities and Exchange Commission on March 12, 2020).</u>
5.1	Legal Opinion of Olshan Frome Wolosky LLP*
10.1	<u>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).</u>
10.2	<u>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).</u>
10.3	<u>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).</u>
10.4	<u>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).</u>
10.5	<u>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).</u>
10.6	<u>Employment Offer Letter with Stephan Jackman, dated November 30, 2018 (Incorporated by reference to Exhibit 6.6 of Form 1-A filed with the Securities and Exchange Commission on March 12, 2020).</u>
10.7	<u>Employment Offer Letter with Kenneth S. Cragun, dated November 30, 2018 (Incorporated by reference to Exhibit 6.7 of Form 1-A/A filed with the Securities and Exchange Commission on February 4, 2020).</u>
10.8	<u>Placement Agent Agreement with Spartan Capital Securities, LLC, dated June 10, 2019 (Incorporated by reference to Exhibit 6.8 of Form 1-A/A filed with the Securities and Exchange Commission on February 4, 2020).</u>
10.9	<u>Stock Pledge Agreement with Ault Life Sciences Fund, LLC, dated June 11, 2019 (Incorporated by reference to Exhibit 6.9 of Form 1-A filed with the Securities and Exchange Commission on March 12, 2020).</u>
10.10	<u>Consulting Agreement with Spartan Capital Securities, LLC, dated June 28, 2017 (Incorporated by reference to Exhibit 6.10 of Form 1-A filed with the Securities and Exchange Commission on March 12, 2020).</u>
10.11	<u>Securities Purchase Agreement with Ault Life Sciences Fund, LLC, dated April 30, 2019 (Incorporated by reference to Exhibit 4.2 of Form 1-A/A filed with the Securities and Exchange Commission on February 4, 2020).</u>
23.1	Consent of Squar Milner LLP, Independent Registered Public Accounting Firm*
23.2	Consent of Olshan Frome Wolosky LLP (included in Exhibit 5.1)*

* To be filed by amendment.

ITEM 17. UNDERTAKINGS

- (a) We hereby undertake:

- (1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
 - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that Paragraphs (a)(1)(i), (ii), and (iii) of this section do not apply if the registration statement is on Form S-1, Form S-3, Form SF-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or, as to a registration statement on Form S-3, Form SF-3 or Form F-3, is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Tampa, Florida, on the 29th day of December 2020.

ALZAMEND NEURO, INC.

Date: December 29, 2020

By: /s/ Stephan Jackman
Stephan Jackman
Chief Executive Officer (Principal Executive Officer)

Date: December 29, 2020

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, each director and officer whose signature appears below constitutes and appoints each of Stephan Jackman and Kenneth S. Cragun, his true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, to sign in any and all capacities any and all amendments or post-effective amendments to this registration statement on Form S-1, and to sign any and all additional registration statements relating to the same offering of securities of the Registrant that are filed pursuant to Rule 462(b) of the Securities Act, and to file the same with all exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, granting such attorney-in-fact and agent full power and authority to do all such other acts and execute all such other documents as he may deem necessary or desirable in connection with the foregoing, as fully as the undersigned may or could do in person, hereby ratifying and confirming all that such attorney-in-fact and agent may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registrant Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
By: <u>/s/ Stephan Jackman</u> Stephan Jackman	Chief Executive Officer and Director (Principal Executive Officer)	December 29, 2020

By: <u>/s/ Kenneth S. Cragun</u> Kenneth S. Cragun	Chief Financial Officer (Principal Financial Officer)	December 29, 2020
By: <u>/s/ Milton Ault, III</u> Milton Ault, III	Executive Chairman of the Board of Directors	December 29, 2020
By: <u>/s/ Henry Nisser</u> Henry Nisser	Executive Vice President, General Counsel and Director	December 29, 2020
By: <u>/s/ William B. Horne</u> William B. Horne	Director	December 29, 2020
By: <u>/s/ Philip Mansour</u> Philip Mansour	Director	December 29, 2020
