As submitted to the Securities and Exchange Commission on November 30, 2016

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

FORM 1-A

### **REGULATION A OFFERING CIRCULAR UNDER THE SECURITIES ACT OF 1933**

### ALZAMEND NEURO, INC.

(Exact name of issuer as specified in its charter)

Delaware

(State of other jurisdiction of incorporation or organization)

### 50 W. Broadway, 3<sup>rd</sup> Floor Salt Lake City, Utah 84101 Telephone: (949) 346-5822

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

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

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

Copy to:

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2834

(Primary Standard Industrial Classification Code Number) 81-1822909 (I.R.S. Employer Identification Number)

This Offering Circular shall only be qualified upon order of the Commission, unless a subsequent amendment is filed indicating the intention to become qualified by operation of the terms of Regulation A.



#### \$50,000,000 MAXIMUM OFFERING AMOUNT MINIMUM INVESTMENT: 50 SHARES (\$100)

This is the initial public offering of securities of Alzamend Neuro, Inc., a Delaware corporation (the "Company"). We are offering a minimum of Fifty (50) shares (the "Minimum Investment") and a maximum of Twenty-Five Million (25,000,000) shares (the "Maximum Offering") of our common stock, par value \$0.0001 (the "Common Stock") at an offering price of \$2.00 per share (the "Shares"). This offering will terminate on the earlier of (i) January 19, 2017, subject to extension for up to one hundredeighty (180) days in the sole discretion of the Company; or (ii) the date on which the Maximum Offering is sold (in either case, the "Termination Date"). If, on the initial closing date, we have sold less than the Maximum Offering, then we may hold one or more additional closings for additional sales, until the earlier of: (i) the sale of the Maximum Offering or (ii) the Termination Date. Until the initial closing date, the proceeds received in the offering will be deposited into an escrow account (the "Escrowed Funds"). Upon the initial closing, the Escrowed Funds will be distributed to the Company and the offered Shares will be issued to the investors therein. If the offering does not close for any reason, the Escrowed Funds will be promptly returned to investors, without deduction and without interest. Transfer Online, Inc. will serve as the escrow agent and will not retain any interest accrued from funds deposited in the escrowat.

We expect to commence the sale of the Shares as of the date on which the offering statement of which this Offering Circular is a part (the "Offering Statement") is qualified by the United States Securities and Exchange Commission (the "SEC").

Investing in our Common Stock involves a high degree of risk. See "Risk Factors" for a discussion of certain risks that you should consider in connection with an investment in our Common Stock.

	Underwriting discount		Proceeds to			Proceeds to other	
		Price to Public	and commissions (1)		Company (2)		persons
Per Share	\$	2.00	\$ 0.20	\$	1.795	\$	0.005
Maximum Offering (3)	\$	50,000,000.00	\$ 5,000,000.00	\$	44,877,000.00	\$	123,000.00

(1) Includes \$5,000,000 for sales commissions although at this time the Company has not determined if it will require these services or selected a service provider

(2) Does not include expenses of the offering, including fees for administrative and escrow agent services, FINRA filing fee, fees for EDGAR document conversion and filing, and website posting fees

GENERALLY, NO SALE MAY BE MADE TO YOU IN THIS OFFERING IF THE AGGREGATE PURCHASE PRICE YOU PAY IS MORE THAN 10% OF THE GREATER OF YOUR ANNUAL INCOME OR YOUR NET WORTH. DIFFERENT RULES APPLY TO ACCREDITED INVESTORS AND NON-NATURAL PERSONS. BEFORE MAKING ANY REPRESENTATION THAT YOUR INVESTMENT DOES NOT EXCEED APPLICABLE THRESHOLDS, WE ENCOURAGE YOU TO REVIEW RULE 251(D)(2)(I)(C) OF REGULATION A. FOR GENERAL INFORMATION ON INVESTING, WE ENCOURAGE YOU TO REFER TO <u>WWW.INVESTOR.GOV</u>.

THE U.S. SECURITIES AND EXCHANGE COMMISSION DOES NOT PASS UPON THE MERITS OF OR GIVE ITS APPROVAL TO ANY SECURITIES OFFERED OR THE TERMS OF THE OFFERING, NOR DOES IT PASS UPON THE ACCURACY OR COMPLETENESS OF ANY OFFERING CIRCULAR OR OTHER SOLICITATION MATERIALS. THESE SECURITIES ARE OFFERED PURSUANT TO AN EXEMPTION FROM REGISTRATION WITH THE COMMISSION; HOWEVER, THE COMMISSION HAS NOT MADE AN INDEPENDENT DETERMINATION THAT THE SECURITIES OFFERED ARE EXEMPT FROM REGISTRATION.

The date of this Offering Circular is November 30, 2016.

-1-

### TABLE OF CONTENTS

	Page
CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS	3
<u>SUMMARY</u>	4
<u>RISK FACTORS</u>	7
USE OF PROCEEDS	28
DILUTION	29
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	31
<u>OUR BUSINESS</u>	36
DESCRIPTION OF PROPERTY	49
DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	49
EXECUTIVE COMPENSATION	52
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	52
PRINCIPAL STOCKHOLDERS	53
DESCRIPTION OF SECURITIES	55
DIVIDEND POLICY	56
PLAN OF DISTRIBUTION	56
ADDITIONAL INFORMATION ABOUT THE OFFERING	56
LEGAL MATTERS	58
EXPERTS	58
WHERE YOU CAN FIND MORE INFORMATION	58
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1

We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where such offers and sales are permitted. You should rely only on the information contained in this Offering Circular. We have not authorized anyone to provide you with any information other than the information contained in this Offering Circular. The information contained in this Offering Circular is accurate only as of its date, regardless of the time of its delivery or of any sale or delivery of our securities. Neither the delivery of this Offering Circular nor any sale or delivery of our securities shall, under any circumstances, imply that there has been no change in our affairs since the date of this Offering Circular. This Offering Circular will be updated and made available for delivery to the extent required by the federal securities laws.

Unless otherwise indicated, data contained in this Offering Circular concerning the business of the Company are based on information from various public sources. Although we believe that these data are generally reliable, such information is inherently imprecise, and our estimates and expectations based on these data involve a number of assumptions and limitations. As a result, you are cautioned not to give undue weight to such data, estimates or expectations.

In this Offering Circular, unless the context indicates otherwise, references to "Alzamend," "we," the "Company," "our," and "us" refer to the activities of and the assets and liabilities of the business and operations of Alzamend Neuro, Inc.

-2-

# CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements under "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Our Business" and elsewhere in this Offering Circular constitute forward-looking statements. Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar matters that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "anticipate", "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "will" and "would" or the negatives of these terms or other comparable terminology.

You should not place undue reliance on forward looking statements. The cautionary statements set forth in this Offering Circular, including in "Risk Factors" and elsewhere, identify important factors which you should consider in evaluating our forward-looking statements. These factors include, among other things:

- · 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.

Although the forward-looking statements in this Offering Circular are based on our beliefs, assumptions and expectations, taking into account all information currently available to us, we cannot guarantee future transactions, results, performance, achievements or outcomes. No assurance can be made to any investor by anyone that the expectations reflected in our forward-looking statements will be attained, or that deviations from them will not be material and adverse. We undertake no obligation, other than as may be required by law, to re-issue this Offering Circular or otherwise make public statements updating our forward-looking statements.



### SUMMARY

This summary highlights selected information contained elsewhere in this Offering Circular. This summary is not complete and does not contain all the information that you should consider before deciding whether to invest in our Common Stock. You should carefully read the entire Offering Circular, including the risks associated with an investment in the company discussed in the "Risk Factors" section of this Offering Circular, before making an investment decision. Some of the statements in this Offering Circular are forward-looking statements. See the section entitled "Cautionary Statement Regarding Forward-Looking Statements."

#### **Company Information**

The Company was formed on February 26, 2016 as Alzamend Neuro, Inc. under the laws of the State of Delaware. The Company was formed to acquire and commercialize patented intellectual property and know how to prevent, treat and cure the crippling and deadly disease, Alzheimer's.

Our mailing address is Alzamend Neuro, Inc., 50 W. Broadway, 3rd Floor, Salt Lake City, UT 84101 and our telephone number is (949) 346-5822. Our website addresses are <u>www.alzamend.com</u> and <u>www.thealzamendstory.com</u>. The information contained therein or accessible thereby shall not be deemed to be incorporated into this Offering Circular.

#### **Our Business**

#### Technology

The first patented solution that Alzamend has licensed to move to commercialization is an immunotherapy vaccine peptide that is designed to be used both as a treatment and vaccine against Alzheimer's (the "**Technology**"). This therapy is intended to work by stimulating the body's own immune system to prevent the formation, and breaks down beta amyloids, which build up in the brain forming a "plaque," and subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's. Immunotherapy is the "treatment of disease by inducing, enhancing, or suppressing an immune response." Immunotherapies are designed to elicit or amplify an immune response and are classified as activation immunotherapies, whereas immunotherapies that reduce or suppress are classified as suppression immunotherapies.

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

We currently have only one product candidate from our Technology, CAO22W, which is in an embryonic stage of development and will require extensive preclinical and 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 CAO22W we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several 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.

#### Market

Since 1990, life expectancy has increased by 6 years and the worldwide average continues to increase. With the increase in the mean age of the population in developed countries, the prevalence of deteriorating neurological diseases has also increased. In the United States alone, 1 in 9 persons over the age of 65 have Alzheimer's disease, with more than 5.3 million Americans living with Alzheimer's. It is estimated that this number will increase to more than 16 million by 2050 if a cure is not found. Many Alzheimer related associations believe the actual number may be as much as 5 times more or 25 million since current stats do not take in account deaths from complications or from related diseases like pneumonia or heart attack. These deaths certificates only list the most immediate cause. The fastest growing age group in the United States is the "over 85" group with 1 in 3 having Alzheimer's. Women are 2½ times more likely to die from Alzheimer's than from cancer. The Company believes that the cost of caring for people with Alzheimer's reached \$226 billion dollars in 2015.



Currently, Alzheimer's is the 6<sup>th</sup> leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. Of the 10 most fatal diseases in the United States, Alzheimer's disease is the only one with no cure, no known way to slow down and no known means of prevention. <sup>1</sup> Alzamend was formed to commercialize patented intellectual property in this space, by funding it from its present state through clinical trials administered by the Federal Drug Administration (the "**FDA**") and ultimately, if successful, to the global market. Additionally, Alzamend is supporting ongoing research at the Byrd Institute, and plans to support others with first rights of refusal on technologies for treating terminal diseases.

### <u>Plans</u>

#### Licensing Fees and ongoing project support for University of South Florida and the Byrd Institute

There are certain initial license fees and milestone payments required to be paid to the University of South Florida and the Byrd Institute, a multi-disciplinary center at the University of South Florida, for the license of the Technology, pursuant to the terms of the Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., a nonstock, nonprofit Florida corporation ("Licensor") and a direct support organization of the University of South Florida ("University") (the "License Agreement").

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

Payment		Due Date	Event
\$	50,000	October 1, 2017	IND Filing
\$	50,000	12 months from IND filing date	Upon first dosing of patient in first Phase I Clinical Trial
\$	175,000	12 months from first patient dosed in Phase I	Upon Completion of first Phase I Clinical Trial
		-	
\$	500,000	24 months from completion of first Phase I Trial	Upon Completion of first Phase II Clinical Trial
\$	1,000,000	12 months from completion of the first Phase II Clinical Trial	Upon first patient treated in a Phase III Clinical Trial
\$	10,000,000	7 years from the Effective Date of the Agreement	Upon FDA Approval

None of the milestones were met as of the date these financial statements included herein were issued.

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 Licensee shall be increased upon such issuance. The amount of the increase shall be determined by multiplying the number of shares then owned by Licensor by a fraction; the numerator of which shall be equal to the number of shares of common stock outstanding immediately after the issuance of additional shares of common stock, and the denominator of which shall be equal to the sum of (i) the number of shares of common stock 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.

<sup>1</sup> Source for figures in this and the preceding paragraph: <u>www.alzheimergpslocator.com</u>

#### - 5 -

Additionally, Alzamend is striving to support the ongoing work required for the commercialization of the Technology and further research associated with other technologies that Alzamend has and will have first right of refusal to commercialize.

### FDA consulting and active project planning management

Alzamend has retained an experienced GMP, FDA, Canadian Health and European Union consulting firm to provide and solicit proposals to lead and manage the entire efforts from the current status of the research through the exit or commercialization of the technologies licensed by the Company. Additionally, the Company intends to retain experienced project management to coordinate all Alzamend internal and external contracting activities with the University of South Florida and Byrd Center project scientific, academic and administrative needs.

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

Alzamend intends to recruit top notch leaders in the Alzheimer's and business communities, who will bring their proven experience and ability to work in a collaborative environment and to focus on the corporate mission, for the scientific advisory board as well as the board of directors (the "Board") itself.

THE OFFERING	
Issuer:	Alzamend Neuro, Inc.
Shares offered:	A minimum of 50 and a maximum of 25,000,000 shares of our Common Stock, at an offering price of \$2.00 per share (the "Shares").
Number of shares of Common Stock outstanding before the offering:	116,600,000 shares.
Number of shares of Common Stock to be outstanding after the offering:	116,600,050 shares, if the Minimum Investment is sold, and 141,600,000 shares, if the Maximum Offering is sold.
Price per share:	\$2.00
Minimum Investment amount:	50 shares at \$2.00 per share, or \$100.00
Maximum Offering:	25,000,000 shares at \$2.00 per share, or \$50,000,000
Use of proceeds:	If we sell all of the shares being offered, our net proceeds (after our estimated offering expenses) will be \$44,877,000. We will use these net proceeds for general corporate purposes.
Risk factors:	Investing in our Common Stock involves a high degree of risk. See "Risk Factors."

- 6 -

### **RISK FACTORS**

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

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

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

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

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

In the aggregate, ownership of the Company's shares of Common Stock by management and affiliated parties, assuming the sale of the Maximum Offering, represents approximately 62% of the issued and outstanding shares of Common Stock. These shareholders, if acting together, will be able to significantly influence all matters requiring approval by shareholders, including the election of directors and the approval of mergers or other business combinations transactions. Our future performance is dependent on the ability to retain key personnel. The Company's performance is substantially dependent on the performance of senior management. The loss of the services of any of its executive officers or other key employees could have a material adverse effect on the Company's business, results of operations and financial condition.

# Certain provisions of our Certificate of Incorporation could allow concentration of voting power in one individual, 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 shareholders.

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



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

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

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

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

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

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

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

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

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

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



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

Since inception, the Company has not generated revenues and has incurred losses and reported losses for the period from February 26, 2016 (inception) to April 30, 2016, totaling \$11,576. As of September 26, 2016, the Company had working capital of \$242,272 and an accumulated deficit of \$654,863. Further, we expect to incur a net loss for the fiscal year ending April 30, 2017, primarily as a result of increased operating expenses. 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. No assurance can be given that additional financing will be available, or if available, will be on acceptable terms. These conditions raise substantial doubt about our ability to continue as a going concern. If adequate working capital is not available we may be forced to discontinue operations, which would cause investors to lose their entire investment. Our auditors have indicated that these conditions raise substantial doubt about the Company's ability to continue as a going concern.

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

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

- · demonstration in future clinical trials that CAO22W is 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 CAO22W; and
- · market acceptance of CAO22W.

We only have one product candidate, CAO22W, which is an embryonic stage of development and will require extensive preclinical and 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 CAO22W we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

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

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

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

Our initiation of operations has resulted in significantly higher operating expenses, which the net proceeds from this Offering, if any, are intended in part to offset. Expansion of our operations, to include the development of CAO22W, may also cause a significant demand on our management, finances and other resources. Our ability to manage the anticipated future growth, should it occur, will depend upon a significant expansion of our accounting and other internal management systems and the implementation and subsequent improvement of a variety of systems, procedures and controls. In addition, we intend to expand the Board and to establish a 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 CAO22W, procedures and controls in an efficient manner at a pace consistent with our business could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that our attempts to expand our marketing, sales, manufacturing and customer support efforts will be successful or will result in additional sales or profitability in any future period.

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

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

In the future, we hope to submit CAO22W and, potentially, other product candidates, for regulatory approval. Currently, however, CAO22W has not 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 candidate, CAO22W. Our near-term prospects, including our ability to finance our company and to enter into strategic collaborations and, ultimately, to generate revenue, are directly dependent upon the successful development and commercialization of CAO22W.

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

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

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

#### CAO22W may not achieve market acceptance, which could limit our ability to generate revenue from new products.

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

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

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

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

We are responsible for the manufacture and supply of CAO22W. The manufacturing of CAO22W necessitates compliance with US FDA, EU EMA 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 CAO22W, the responsibility to obtain market authorization for CAO22W remains with us. As such, even if we could potentially have a claim against one or more third parties, we are legally liable for any noncompliance related to CAO22W and we expect to retain legal responsibility for any future product candidates as well.

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

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



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

The development and commercialization of new therapy and vaccine products is highly competitive. We will face competition with respect to CAO22W, and will face competition with respect to any 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 CAO22W, we also face potential competition from other drug candidates in development by other companies. Our potential competitors include large health care companies, such as Celgene, 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 experienced pharmaceutical and biotechnology companies or have been partnered with such companies, which may give them development, regulatory and marketing advantages over our products.

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

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

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

# Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of CAO22W, or limit the scope of any approved label or market acceptance.

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

- · regulatory authorities may interrupt, delay or halt clinical trials;
- · regulatory authorities may deny regulatory approval of CAO22W;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy (*"REMS"*), in connection with approval, if any;
- · regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS of any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;

- 12 -

- 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 CAO22W is unlikely to receive regulatory approval or is unlikely to be successfully commercialized. In addition, regulatory agencies, an Institutional Review Board ("**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 ever forced to suspend or terminate a clinical trial of CAO22W or any other product candidate that we may in the future develop, the commercial prospects for that product will be harmed and our ability to generate acceptance of the affected 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 CAO22W and materially impair our ability to generate revenue from the commercialization of CAO22W either by us or by any commercial partners that we may develop a relationship with in the future and could have a material adverse effect on our reputation, business, results of operations and financial condition.

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

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

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

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our eventual partners may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby 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.

- 13 -

### 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 may be 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.

CAO22W 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 subjects us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our products must be stored and transported at temperatures within a certain range, which is known as "strict cold chain" storage and transportation. If these environmental conditions deviate, our products' remaining shelf lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches, any of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

Generally speaking, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. For instance, because a large percentage of subjects in our pivotal trials for CAO22W may be enrolled at sites outside the U.S., differences in efficacy results between U.S. and non-U.S. sites could cause the FDA to require additional trials. In the event that:

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

### - 14 -

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

### Clinical trials for CAO22W are 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 CAO22W are expected to continue for several years and may even take significantly longer to complete. In addition, we, the FDA, an IRB, or other regulatory authorities, including in the U.S., EU and elsewhere, may suspend, delay or terminate our clinical trials at any time, for various reasons, including:

- · lack of effectiveness of CAO22W during clinical trials;
- · discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- · slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may have withdrawn due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to manufacturing or regulatory constraints;
- · inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a trial, including experiencing "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- · changes in applicable regulatory policies and regulations;
- · delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- · unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of any contract research organizations ("CROs") that we may partner with in the future, or other third-party contractors, to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, any CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- · scheduling conflicts with participating clinicians and clinical institutions;
- · failure to design appropriate clinical trial protocols; or
- · regulatory concerns with pharmaceutical products generally and the potential for abuse.

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

- 15 -

# 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 CAO22W.

The research, testing, manufacturing, labeling, approval, sale, marketing and testing of CAO22W are subject to extensive regulation by regulatory authorities in the U.S. and Europe, and regulatory requirements applicable to our product differ from country to country. Neither we nor any commercial partner is permitted to market any of our current or future product candidates in the U.S. until we receive approval from the FDA of a BLA. Obtaining approval of 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 Investigational New Drug ("IND") application, 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 BLA, which must occur before a drug can be marketed or sold.

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

In addition, separate regulatory approvals are required in order to market any product in many jurisdictions, including the U.S., the European Economic Area, which consists of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein, and many others. Approval procedures vary among countries and can involve additional studies and testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by the FDA does not ensure approval by regulatory authorities or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approvals 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 and any product candidates, if any, if approved, will be subject to labeling and manufacturing requirements and could be subject to other restrictions. Failure to comply with these regulatory requirements or the occurrence of unanticipated problems with our products could result in significant penalties.

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



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

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

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

If we are successful in commercializing CAO22W and any of our future product candidates, regulations of the FDA and of 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 CAO22W or any of our future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

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

requests for additional endpoints or studies;

- 17 -

- · 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 financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products could materially and adversely affect our business, results of operations and financial condition.

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

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

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

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

- 18 -

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

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

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

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

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

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

Our future growth and success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Philip Mansour, our Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our current or future product pipeline, completion of our planned development efforts or the commercialization of CAO22W. Although we are negotiating these agreements, they do not provide for a fixed term of service, and does not contain any competition or non-solicitation clauses after the termination of employment. It is possible that current or former employees of the Company could put forward claims for an alleged right to our patents and demand compensation therefor. If one or more of the key personnel were to leave us and engage in competing operations, our business, results of operations, nor has any departure of key personnel had any material effect on our company.



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

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

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

We are subject to various claims and legal actions arising in the ordinary course of its 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 successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of CAO22W.

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

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

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

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

Our ability to execute our business plan and to comply with regulatory requirements with respect to data control and data integrity depends, in part, on the continued and uninterrupted performance of our information technology systems ("IT systems"). These systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, there are no assurances that electronic break-ins, computer viruses and similar disruptive problems. 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.

- 20 -

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

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

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

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

#### **Risks Related to Our Intellectual Property**

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

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

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

-21-

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

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

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

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

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

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

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay research, development, manufacturing or sales of CAO22W. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are 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 CAO22W or any of our potential future product candidates are not adequate, we may not be able to compete effectively in our market.

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

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

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

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

We will also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or had access to our proprietary information, nor that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not 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 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 CA022W.

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

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

### **Risks Relating to this Offering**

## There has been no public market for our Common Stock prior to this offering, and an active market in which investors can resell their shares may not develop.

Prior to this offering, there has been no public market for our Common Stock. We cannot predict the extent to which an active market for our Common Stock will develop or be sustained after this offering, or how the development of such a market might affect the market price of our Common Stock. The initial offering price of our Common Stock in this offering is based on a number of factors, including market conditions in effect at the time of the offering, and it may not be in any way indicative of the price at which our shares will trade following the completion of this offering. Investors may not be able to resell their shares at or above the initial offering price.



### Investors in this offering will experience immediate and substantial dilution

If all of the shares offered hereby are sold, investors in this offering will own less than 18% of the then outstanding shares of common stock, but will have paid over 97% of the total consideration for our outstanding shares, resulting in a dilution of \$1.679 per share. See "Dilution" within this Offering Circular.

### The market price of our Common Stock may fluctuate, and you could lose all or part of your investment.

The offering price for our Common Stock is based on a number of factors. The price of our Common Stock may decline following this Offering. The stock market in general, and the market price of our Common Stock, will likely be subject to fluctuation, whether due to, or irrespective of, our operating results, financial condition and prospects.

Our financial performance, our industry's overall performance, changing consumer preferences, technologies and advertiser requirements, government regulatory action, tax laws and market conditions in general could have a significant impact on the future market price of our Common Stock. Some of the other factors that could negatively affect our share price or result in fluctuations in our share price includes:

- · actual or anticipated variations in our periodic operating results;
- · increases in market interest rates that lead purchasers of our Common Stock to demand a higher yield;
- · changes in earnings estimates;
- · changes in market valuations of similar companies;
- · actions or announcements by our competitors;
- · adverse market reaction to any increased indebtedness we may incur in the future;
- · additions or departures of key personnel;
- · actions by stockholders;
- · speculation in the press or investment community; and
- our intentions and ability to list our Common Stock on a national securities exchange and our subsequent ability to maintain such listing.

### We do not expect to declare or pay dividends in the foreseeable future.

We do not expect to declare or pay dividends in the foreseeable future, as we anticipate that we will invest future earnings in the development and growth of our business. Therefore, holders of our Common Stock will not receive any return on their investment unless they sell their securities, and holders may be unable to sell their securities on favorable terms or at all.

### Sales of our common stock under Rule 144 could reduce the price of our stock.

There are currently 116,600,000 shares of our common stock held by non-affiliates and no shares held by affiliates that Rule 144 of the Securities Act of 1933 defines as restricted securities that can only be resold if the conditions of Rule 144 are met. In general, persons holding restricted securities, including affiliates, must hold their shares for a period of at least six months, may not sell more than one percent of the total issued and outstanding shares in any 90-day period, and must resell the shares in an unsolicited brokerage transaction at the market price. However, Rule 144 will only be available for resale in the 90 days after the Company files its semi-annual reports on Form 1-SA and annual reports on Form 1-K, unless the Company voluntarily files interim quarterly reports on Form 1-U, which the Company has not yet decided to do. The availability for sale of substantial amounts of common stock under Rule 144 could reduce prevailing market prices for our securities.



#### Because we do not have an audit or compensation committee, shareholders will have to rely on our directors, none of whom is independent, to perform these functions.

We do not have an audit or compensation committee comprised of an independent director. Indeed, we do not have any audit or compensation committee. The Board performs these functions as a whole. No members of the Board are an independent director. Thus, there is a potential conflict in that board members who are also part of management will participate in discussions concerning management compensation and audit issues that may affect management decisions.

# Our failure to maintain effective internal controls over financial reporting could have an adverse impact on us

We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal control over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting, disclosure of management's assessment of our internal controls over financial reporting or disclosure of our public accounting firm's attestation to or report on management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

Upon the completion of this offering, we may elect to become a public reporting company under the Securities and Exchange Act of 1934 (the "Exchange Act"), and thereafter publicly report on an ongoing basis as an "emerging growth company" under the reporting rules set forth under the Exchange Act. If we elect not to do so, we will be required to publicly report on an ongoing basis under the reporting rules set forth in Regulation A for Tier 2 issuers. In either case, we will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not "emerging growth companies," and our stockholders could receive less information than they might expect to receive from more mature public companies.

Upon the completion of this offering, we may elect to become a public reporting company under the Exchange Act. If we elect to do so, we will be required to publicly report on an ongoing basis as an "emerging growth company" (as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not "emerging growth companies," including but not limited to:

- · not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- taking advantage of extensions of time to comply with certain new or revised financial accounting standards;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We would remain an "emerging growth company" for up to five years, although if the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of any October 31 before that time, we would cease to be an "emerging growth company" as of the following April 30.



If we elect not to become a public reporting company under the Exchange Act, we will be required to publicly report on an ongoing basis under the reporting rules set forth in Regulation A for Tier 2 issuers. The ongoing reporting requirements under Regulation A are more relaxed than for "emerging growth companies" under the Exchange Act. The differences include, but are not limited to, being required to file only annual and semiannual reports, rather than annual and quarterly reports. Annual reports are due within 120 calendar days after the end of the issuer's fiscal year, and semiannual reports are due within 90 calendar days after the end of the first six months of the issuer's fiscal year.

In either case, we will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not "emerging growth companies," and our stockholders could receive less information than they might expect to receive from more mature public companies.

### The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we will incur significant legal, accounting and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We also will incur costs associated with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Act and related rules implemented or to be implemented by the SEC. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. For so long as we qualify as an emerging growth company under the JOBS Act, we may make certain elections that would subject us to reduced reporting and corporate governance requirements. Nonetheless, we expect the rules and regulations associated with being a public company to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept constraints on policy limits and coverage or incur substantially higher costs to obtain coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our board committees or as our executive officers and may divert management's attention. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

# The preparation of our financial statements involves the use of estimates, judgments and assumptions, and our financial statements may be materially affected if such estimates, judgments or assumptions prove to be inaccurate.

Financial statements prepared in accordance with accounting principles generally accepted in the United States of America (*GAAP*<sup>\*</sup>) typically require the use of estimates, judgments and assumptions could reasonably be used that would have a material effect on such financial statements, and changes in these estimates, judgments and assumptions may occur from period to period over time. These estimates, judgments and assumptions are inherently uncertain and, if our estimates were to prove to be wrong, we would face the risk that charges to income or other financial statement changes or adjustments would be required. Any such charges or changes could harm our business, including our financial condition and results of operations and the price of our securities. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of the accounting estimates, judgments and assumptions that we believe are the most critical to an understanding of our consolidated financial statements and our business.

### If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our Common Stock could be negatively affected.

Any trading market for our Common Stock will be influenced in part by any research reports that securities industry analysts publish about us. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our Common Stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage or us, the market price and market trading volume of our Common Stock could be negatively affected.

# Our management has broad discretion as to the use of certain of the net proceeds from this offering.

We intend to use approximately \$39 million of the net proceeds from this offering (if we sell all of the shares being offered) for working capital and other general corporate purposes. However, we cannot specify with certainty the particular uses of such proceeds. Our management will have broad discretion in the application of the net proceeds designated for use as working capital or for other general corporate purposes. Accordingly, you will have to rely upon the judgment of our management with respect to the use of these proceeds. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our Common Stock may not desire or that may not yield a significant return or any return at all. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value. Please see "Use of Proceeds" below for more information.



### **USE OF PROCEEDS**

Assuming the sale by us of the Maximum Offering of \$50,000,000 and estimated expenses of \$5,123,000, the total net proceeds to us would be \$44,877,000, which we currently intend to use as set forth below. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. As of the date of this Offering Circular, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of common stock. Accordingly, we will retain broad discretion over the use of these proceeds, if any. The following table represents Management's best estimate of the uses of the net proceeds received from the sale of common stock assuming the sale of, respectively, 100%, 75%, 50% and 25% of the shares offered for sale in this offering.

Offering							
		100%		75%		50%	25%
Licensing Fees and Ongoing project support for University of							
South Florida and the Byrd Institute	\$	375,000	\$	375,000	\$	375,000	\$ 375,000
FDA consulting and active project planning management	\$	2,500,000	\$	2,500,000	\$	2,500,000	\$ 2,500,000
Establishment of advisory board, initial meetings, corporate							
development and initial consulting	\$	2,625,000	\$	2,362,500	\$	1,968,750	\$ 1,575,000
Working Capital	\$	39,377,000	\$	28,389,500	\$	17,533,250	\$ 6,677,000
TOTAL	\$	44,877,000	\$	33,627,000	\$	22,377,000	\$ 11,127,000

The amounts set forth above are estimates, and we cannot be certain that actual costs will not vary from these estimates. Our management has significant flexibility and broad discretion in applying the net proceeds received in this Offering. We cannot assure you that our financial performance estimates will prove to be accurate or that unforeseen events, problems or delays will not occur that would require us to seek additional debt and/or equity funding, which may not be available on favorable terms, or at all. See "Risk Factors."

Alzamend will incur fundamental legal, executive, operational, financial, and support expenses while in the initial phases of the company. There will be no full time staff dedicated to the project until such time as necessary to insure these costs are kept to a minimum. Travel will be required to facilitate the timely setup and project management of all facets of the Company. The Company intends to use a part of the proceeds raised from this offering, if any, to fund the compensation payable to its two officers and its chairman of the board of directors through the Master Services Agreement described under "Our Business – Employees" below.



# DILUTION

If you purchase shares in this offering, your ownership interest in our Common Stock will be diluted immediately, to the extent of the difference between the price to the public charged for each share in this offering and the net tangible book value per share of our Common Stock after this offering.

Our historical net tangible book value as of April 30, 2016 was (\$106) or \$0.00 per then outstanding share of our Common Stock. Historical net tangible book value per share equals the amount of our total tangible assets less total liabilities, divided by the total number of shares of our Common Stock outstanding, all as of the date specified.

Our net tangible book value as of August 10, 2016, before accounting for this offering, was \$511,939 or \$0.004 per then-outstanding share of our Common Stock. Net tangible book value per share equals the amount of our total tangible assets less total liabilities, divided by the total number of shares of our Common Stock outstanding, as of the date specified.

The following table illustrates the per share dilution to new investors discussed above, assuming the sale of, respectively, 100%, 75%, 50% and 25% of the shares offered for sale in this offering (after our estimated offering expenses of \$5,123,000, \$3,873,000, \$2,623,000 and \$1,373,000, respectively):

	100%	75%	50%	25%
Price to the public charged for each share in this offering	\$ 2.00	\$ 2.00	\$ 2.00	\$ 2.00
Historical net tangible book value per share as of August 10, 2016 (1)	\$ 0.004	\$ 0.004	\$ 0.004	\$ 0.004
Increase in net tangible book value per share attributable to new investors in this				
offering (2)	\$ 0.317	\$ 0.248	\$ 0.173	\$ 0.091
Net tangible book value per share, after this offering	\$ 0.321	\$ 0.252	\$ 0.177	\$ 0.095
Dilution per share to new investors	\$ 1.679	\$ 1.748	\$ 1.823	\$ 1.905

(1) Based on net tangible book value as of August 10, 2016 of \$511,939 and 116,600,000 outstanding shares of Common stock.

(2) After deducting our estimated offering expenses of \$5,123,000, \$3,873,000, \$2,623,000 and \$1,373,000, respectively.

The following tables set forth, assuming the sale of, respectively, 100%, 75%, 50% and 25% of the shares offered for sale in this offering (after our estimated offering expenses of \$5,123,000, \$3,873,000, \$2,623,000 and \$1,373,000, respectively), as of August 10, 2016, the total number of shares previously sold to existing stockholders, the total consideration paid for the foregoing and the average price paid per share. As the table shows, new investors purchasing shares may in certain circumstances pay an average price per share substantially higher than the average price per share paid by our existing stockholders:

- 29 -

	Shares Purchased		Total Con	sideration	Average Price		
	Number	Percentage	Amount	Percentage	Per Share		
Assuming 100% of Shares Sold:							
Existing stockholders	116,600,000	82.3% \$	1,009,310	2.2%	6 0.009		
New Investors	25,000,000	17.7% \$	44,877,000	97.8%			
Total	141,600,000	100.0% §	45,886,310	100.0%	6 0.324		
	Shares Pu	irchased	Total Con	sideration	Average Price		
	Number	Percentage	Amount	Percentage	Per Share		
Assuming 75% of Shares Sold:							
Existing Stockholders	116,600,000	86.1% \$	1,009,310	2.9% \$	6 0.009		
New Investors	18,750,000	13.9% \$	33,627,000	97.1%	5 1.794		
Total	135,350,000	100.0% \$	34,636,310	100.0%	6 0.256		
	Shares Pu	rchased	Total Con	sideration	Average Price		
	Shares Pu Number	rchased Percentage	Total Con Amount	sideration Percentage	Average Price Per Share		
Assuming 50% of Shares Sold:					0		
Assuming 50% of Shares Sold: Existing Stockholders			Amount		Per Share		
8	Number	Percentage           90.3%         \$           9.7%         \$	Amount 1,009,310	Percentage	Per Share           6         0.009		
Existing Stockholders	Number 116,600,000	Percentage 90.3% \$	Amount 5 1,009,310 5 22,377,000	Percentage 4.3%	Per Share           5         0.009           5         1.790		
Existing Stockholders New Investors	Number 116,600,000 12,500,000	Percentage           90.3%         \$           9.7%         \$           100.0%         \$	Amount 5 1,009,310 5 22,377,000	Percentage           4.3%         5           95.7%         5           100.0%         5	Per Share           5         0.009           5         1.790		
Existing Stockholders New Investors	Number 116,600,000 12,500,000 129,100,000	Percentage           90.3%         \$           9.7%         \$           100.0%         \$           irchased         \$	Amount           5         1,009,310           5         22,377,000           5         23,386,310	Percentage           4.3%         5           95.7%         5           100.0%         5	Per Share           6         0.009           5         1.790           5         0.181		
Existing Stockholders New Investors	Number 116,600,000 12,500,000 129,100,000 Shares Pu	Percentage           90.3%         \$           9.7%         \$           100.0%         \$	Amount           5         1,009,310           5         22,377,000           5         23,386,310           Total Const	Percentage           4.3%         5           95.7%         5           100.0%         5           sideration         5	Per Share 5 0.009 5 1.790 5 0.181 Average Price		
Existing Stockholders New Investors Total	Number 116,600,000 12,500,000 129,100,000 Shares Pu	Percentage           90.3%         \$           9.7%         \$           100.0%         \$           irchased         \$	Amount           3         1,009,310           3         22,377,000           3         23,386,310           Total Cons           Amount	Percentage           4.3%         5           95.7%         5           100.0%         5           sideration         5	Per Share           6         0.009           5         1.790           6         0.181           Average Price         Per Share		
Existing Stockholders New Investors Total Assuming 25% of Shares Sold:	Number           116,600,000           12,500,000           129,100,000           Shares Pu           Number	Percentage           90.3%         \$           9.7%         \$           100.0%         \$           rchased         \$           Percentage         \$	Amount           3         1,009,310           3         22,377,000           3         23,386,310           Total Cons           Amount           5         1,009,310	Percentage           4.3%         9           95.7%         9           100.0%         9           sideration         9           Percentage         9	Per Share           5         0.009           5         1.790           5         0.181   Average Price Per Share		

- 30 -

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

# Summary of Results

The following table summarizes the results of our operations for the period from inception on February 26, 2016 to fiscal year end April 30, 2016.

ALZAMEND	NEURO	INC
ALLAMEND	NEUKU,	INC

Statement of Operations February 26, 2016 (Inception) to April 30, 2016		
REVENUE	\$	
OPERATING EXPENSES General and administrative expenses NET LOSS		1,576 1,576)
Basic and diluted net loss per common share	<u>\$</u>	(0.01)
Basic and diluted weighted average common shares outstanding	2,07	6,154

# Fiscal period ended April 30, 2016

Revenues. Alzamend Neuro, Inc. is a preclinical development stage company purposed to commercialize patented intellectual property to prevent, treat and cure the crippling and deadly disease, Alzheimer's. No revenues in the fiscal year ended April 30, 2016.

Cost of Goods Sold. The Company remains in developmental stage and, in conjunction with not having any operational revenue, it has incurred no Cost of Goods and Services Sold.

General and administrative. General and administrative expenses for the fiscal year ending April 30, 2016 were \$11,576. Legal and professional expenses represented \$4,063 of our total general and administrative expenses. These expenses were related to the cost of establishing the company and incorporation, initial business and infrastructure development and other various legal fees for raising capital for the Company. The remaining general and administrative expenses of \$7,513 primarily consisted of payments for transfer agent fees, travel, stock based compensation and other office expenses.

Net loss. For the foregoing reasons, our net loss was \$11,576 for our fiscal year ending April 30, 2016.

-	31	-

### Liquidity, Capital Resources and Plan of Operations

### **Going Concern**

Our financial statements appearing elsewhere in this Offering Circular have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is contingent upon its ability to raise additional capital as required. During the period from inception (February 26, 2016) through April 30, 2016, the Company incurred operating losses of \$11,576. Initially, we intend to finance our operations through equity and debt financings.

During April 2016, the Company entered into subscription agreements with multiple investors. The Company issued and sold to these investors 46,400,000 shares of its common stock at \$.0001 per share. The issuance resulted in aggregate gross proceeds to the Company of \$4,640, of which \$1,105 was received in April 2016. and the remainder of \$3,535 was received in May 2016. On April 1, 2016, the Company entered into a subscription agreement with MCKEA Holdings, LLC ( "MCKEA"). The Company issued and sold to MCKEA 1,000,000 shares of Series A Preferred Shares that are convertible into 80,000,000 shares of Common Stock that carry the voting power of 200,000,000 shares of common stock. Kristine L. Ault, the wife of Milton C. Ault III, Chairman of the Company's Board, is the manager and owner of MCKEA. The issuance resulted in aggregate gross proceeds to the Company of \$8,000, of which \$5,000 was received in April 2016 and \$3,000 has not yet been received and recorded as a subscription receivable by reducing stockholders' equity.

Further, subsequent to year end the Company has sold additional equity securities. During May 2016, the Company entered into subscription agreements with multiple investors. The Company issued and sold to these investors 46,700,000 shares of its common stock at \$.0001 per share. The issuance resulted in aggregate gross proceeds to the Company of \$4,670. The Company anticipates payment in full for these shares, of \$4,670, by August 31, 2016 and it has recorded a receivable at May 31, 2016. Through August 16, 2016, \$1,870 of the outstanding receivable has been paid.

On May 30, 2016, the Company entered into subscription agreements for the sale of 360,000 shares of Series A Preferred Stock to two investors at \$0.008/share for an aggregate purchase price of \$2,880. The Company received \$288 in cash and recorded a receivable for \$2,592. The Series A Preferred Stock is convertible into 28,800,000 shares of Common Stock.

On June 23, 2016 and July 6, 2016, the Company entered into subscription agreements with EAV, LLC for the purchase of 500 units at \$1,000 for each unit purchased. Each unit consisted of 23,500 shares of Common Stock. In aggregate, EAV purchased a total of 1,000 units, representing 23,500,000 shares of Common Stock for an aggregate of \$1,000,000, or approximately \$0.0426 per share, pursuant to the terms of a Private Placement Memorandum dated June 3, 2016. Payment for the 1,000 units was received between July 7, 2016 and August 2, 2016. In conjunction with the Private Placement Memorandum, the Company incurred \$100,000 in placement fees to Palladium Capital Advisors, LLC, and \$39,885 in legal and filing fees, resulting in net proceeds to the Company of \$860,115.

Finally, during the period from May 11, 2016 to June 3, 2016, JLA Realty Associates, LLC loaned \$75,000 to the Company. As consideration for the loan, the Company issued JLA Realty a promissory note in the aggregate principal amount of \$75,000 (the "JLA Note"). The JLA Note provided for a loan fee of \$5,000 and was due 60 days from the date of the loan. The JLA Note, including the loan fee, was repaid on July 7, 2016.

The Company must raise additional equity or debt financing. However, no assurances can be made that the Company will be successful obtaining additional equity or debt financing, or that ultimately the Company will achieve profitable operations and positive cash flow.

Our auditors have indicated that these conditions raise substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or amounts and classification of liabilities that might result from this uncertainty.

Since inception, our principal sources of operating funds have been proceeds from debt and equity financing including the sale of Common Stock to initial investors known to management and principal shareholders of the Company. We do not expect that our current cash on hand will fund our existing operations. We will need to raise additional capital in order execute our business plan and growth goals for at least the next twelve-month period thereafter. If the Company is unable to raise sufficient additional funds, it will have to execute a slower than planned growth path, reduce overhead and scale back its business plan until sufficient additional capital is raised to support further operational expansion and growth. There can be no assurance that such a plan will be successful.

- 32 -

### **Current Plan of Operations**

Our plan of operations is currently focused on the development of our one product candidate, CAO22W, which is in an embryonic stage of development. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of CAO22W and ongoing internal research and development programs. At this time, we cannot reliably estimate the nature, timing or aggregate amount of such costs. CAO22W will require extensive preclinical and clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it or any successors could provide us with any revenue. Further, we intend to continue to build our corporate and operational infrastructure and to build interest in our product candidate, CAO22Q, in each of the medical, scientific and investment communities, with the ultimate goal of attempting to raise sufficient financing or effect partnering transactions with biopharmaceutical companies to fund the costly later-stage clinical development required to achieve successful commercialization of CAO22W.

As noted above, the continuation of our current plan of operations requires us to raise significant additional capital immediately. If we are successful in raising capital through the sale of shares offered for sale in this Offering Circular we believe that the Company will have sufficient cash resources to fund its plan of operations for the next twelve months. If we are unable to do so, our ability to continue as a going concern will be in jeopardy, likely causing us to curtail and possibly cease operations.

We continually evaluate our plan of operations discussed above to determine the manner in which we can most effectively utilize our limited cash resources. The timing of completion of any aspect of our plan of operations is highly dependent upon the availability of cash to implement that aspect of the plan and other factors beyond our control. There is no assurance that we will successfully obtain the required capital or revenues, or, if obtained, that the amounts will be sufficient to fund our ongoing operations. The inability to secure additional capital would have a material adverse effect on us, including the possibility that we would have to sell or forego a portion or all of our assets or cease operations. If we discontinue our operations, we will not have sufficient funds to pay any amounts to our stockholders.

Even if we raise additional capital in the near future, if our current and planned clinical trials for CAO22W in the United States do not demonstrate continuing progress toward taking our product to market, our ability to raise additional capital in the future to fund our product development efforts would likely be seriously impaired. The ability of a biotechnology company, such as Alzamend, to raise additional capital in the marketplace to fund its continuing development operations, is conditioned upon moving the development of products toward regulatory approval and commercialization. If in the future we are not able to demonstrate adequate progress in the development of our product, we will not be able to raise the capital we need to continue our then current business operations and business activities, and we will likely not have sufficient liquidity or cash resources to continue operating.

Because our working capital requirements depend upon numerous factors, including progress of our research and development programs, pre-clinical 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, there can be no assurance that our current cash resources will be sufficient to fund our operations. At present, we have no committed external sources of capital, and do not expect any significant product revenues for the foreseeable future. Thus, we will require immediate additional financing to fund future operations. There can be no assurance, however, that we will be able to obtain funds on acceptable terms, if at all.

- 33 -

### **Credit Facilities**

We do not have any credit facilities or other access to bank credit.

## Capital Expenditures

We do not have any contractual obligations for ongoing capital expenditures at this time. We do, however, purchase equipment and software necessary to conduct our operations on an as needed basis.

# **Contractual Obligations, Commitments and Contingencies**

On May 1, 2016, the Company entered into a Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., a nonstock, nonprofit Florida corporation ("Licensor") and a direct support organization of the University of South Florida ("University") (the *"License Agreement"*). Licensor granted the Company a royalty bearing, exclusive worldwide license, limited to the field of Alzheimer's Immunotherapy and Diagnostics, under United States Patent No. 8,188,046, entitled "Amyloid Beta Peptides and Methods of Use", filed April 7, 2009 and granted May 29, 2012.

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

Payment		Due Date	Event
¢	<b>5</b> 0,000	0.1.1.2015	
\$	50,000	October 1, 2017	IND Filing
\$	50,000	12 months from IND 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 Dhose II Clinical Trial	Unon First restions tracted in a Dhase III 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 Approval

None of the milestones were met as of the date these financial statements were issued.

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 Licensee shall be increased upon such issuance. The amount of the increase shall be determined by multiplying the number of shares then owned by Licensor by a fraction; the numerator of which shall be equal to the number of shares of common stock outstanding immediately after the issuance of additional shares of common stock, and the denominator of which shall be equal to the sum of (i) the number of shares of common stock 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.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements.

### Quantitative and Qualitative Disclosures about Market Risk

In the ordinary course of our business, we are not exposed to market risk of the sort that may arise from changes in interest rates or foreign currency exchange rates, or that may otherwise arise from transactions in derivatives.

### Contingencies

Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company's management, in consultation with its legal counsel as appropriate, assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company, in consultation with legal counsel, evaluates the perceived merits of any legal proceedings or unasserted claims, as well as the perceived merits of the amount of relief sought or expected to be sought therein. If the assessment of a contingency indicates it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates a potentially material loss contingency is not probable, but is reasonably possible, or is probable, but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed.

### **Relaxed Ongoing Reporting Requirements**

Upon the completion of this offering, we may elect to become a public reporting company under the Exchange Act. If we elect to do so, we will be required to publicly report on an ongoing basis as an "emerging growth company" (as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not "emerging growth companies," including but not limited to:

- · not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- taking advantage of extensions of time to comply with certain new or revised financial accounting standards;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not
  previously approved.

We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We would remain an "emerging growth company" for up to five years, though if the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of any October 31 before that time, we would cease to be an "emerging growth company" as of the following April 30.

If we elect not to become a public reporting company under the Exchange Act, we will be required to publicly report on an ongoing basis under the reporting rules set forth in Regulation A for Tier 2 issuers. The ongoing reporting requirements under Regulation A are more relaxed than for "emerging growth companies" under the Exchange Act. The differences include, but are not limited to, being required to file only annual and semiannual reports, rather than annual and quarterly reports. Annual reports are due within 120 calendar days after the end of the issuer's fiscal year.



In either case, we will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not "emerging growth companies," and our stockholders could receive less information than they might expect to receive from more mature public companies.

# **OUR BUSINESS**

# <u>Technology</u>

The first patented solution that Alzamend has licensed to move to commercialization is an immunotherapy vaccine peptide that is designed to be used both as a treatment and vaccine against Alzheimer's (the "Technology"). This therapy is intended to work by stimulating the body's own immune system to prevent the formation, and breaks down beta amyloids, which build up in the brain forming a "plaque," and subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's. Immunotherapy is the "treatment of disease by inducing, enhancing, or suppressing an immune response." Immunotherapies are designed to elicit or amplify an immune response and are classified as activation immunotherapies, whereas immunotherapies that reduce or suppress are classified as suppression immunotherapies.

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

We currently have only one product candidate from our Technology, CAO22W, which is in an embryonic stage of development and will require extensive preclinical and 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 CAO22W we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several 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.

## <u>Market</u>

Since 1990, life expectancy has increased by 6 years and the worldwide average continues to increase. With the increase in the mean age of the population in developed countries, the prevalence of deteriorating neurological diseases has also increased. In the United States alone, 1 in 9 persons over the age of 65 have Alzheimer's disease, with more than 5.3 million Americans living with Alzheimer's. It is estimated that this number will increase to more than 16 million by 2050 if a cure is not found. The Company believes that the cost of caring for people with Alzheimer's reached \$226 billion dollars in 2015.

Currently, Alzheimer's is the 6<sup>th</sup> leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. Alzamend was formed to commercialize patented intellectual property in this space, by funding it from its present state through FDA Clinical Trials and ultimately, if successful, potentially to the global market. Additionally, Alzamend is supporting ongoing research at the Byrd Institute, and plans to support others with first rights of refusal on technologies for treating terminal diseases.



# <u>Plans</u>

## Licensing Fees and ongoing project support for University of South Florida and the Byrd Institute

There are certain initial license fees and milestone payments required to be paid to the University of South Florida and the Byrd Institute, a multi-disciplinary center at the University of South Florida, for the license of the Technology, pursuant to the terms of the License Agreement as discussed above. Additionally, Alzamend is striving to support the ongoing work required for the commercialization of the Technology and further research associated with other technologies that Alzamend has and will have first right of refusal to commercialize.

FDA consulting and active project planning management

Alzamend has retained an experienced GMP, FDA, Canadian Health and European Union consulting firm to provide and solicit proposals to lead and manage the entire efforts from the current status of the research through the exit or commercialization of the technologies licensed by the Company. Additionally, the Company intends to retain experienced project management to coordinate all Alzamend internal and external contracting activities with the University of South Florida and Byrd Center project scientific, academic and administrative needs.

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

Alzamend intends to recruit top notch leaders in the Alzheimer's and business communities, who will bring their proven experience and ability to work in a collaborative environment and to focus on the corporate mission, for the scientific advisory board as well as the Board itself.

Immediate Objectives and Regulatory Considerations:

Management believes that the critical execution elements for the Company in the next two quarters are as follows:

- · Capitalize the Company through this
- Offering;
- · Establish corporate offices and secure initial core
- team;
- · Secure the first set of IP from University of South Florida with patent and license
- payments;
- Expand the Company's Board;
- · Form a scientific advisory board;
- · Select GMP, FDA, and European Union consulting organization to oversee regulatory and develop multi-phase plan; and
- Fund additional research with USF and Byrd institute and secure first right of refusal on additional intellectual property.

Additionally, the Company's financial strategy is to join either the NYSE, AMEX or NASDAQ to maximize the benefit to shareholders and the exposure to sources of finance and other resources that the Company will require through all of its endeavors.

# **Our Product Candidates**

Currently, the Company has one product candidate, CAO22W. The novelty and rationale of using CAO22W as therapy for Alzheimer's is described below:

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

Recent progress in the treatment of neurodegenerative diseases, such as Alzheimer's, has demonstrated that both active and passive immunotherapies can slow down, to some degree, the progress of disease as demonstrated in clinical trials through the measurement of neuropathological and cognitive/behavioral endpoints. However, no current therapy focuses on immune modulation or addresses an impaired immune system, which can obviously adversely affect the efficacy of active vaccines and immunotherapies. Therefore, it is reasoned that strategies to strengthen the immune system in the aged, who are most susceptible to the development of Alzheimer's, could greatly enhance the effectiveness of immune-based approaches against Alzheimer's. Our novel immune-based methodology attempts to inhibit the natural process of immunological aging by restoring the balance of immune system through immunomodulation.



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

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

## **Market Opportunity**

The Company believes that the cost of caring for people with Alzheimer's reached 226 billion dollars in 2015. Currently, Alzheimer's is the  $6^{\text{th}}$  leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. Alzamend was formed to commercialize patented intellectual property in this space, by funding it from its present state through FDA Clinical Trials and ultimately, if successful, to the global market. Additionally, Alzamend is supporting ongoing research at the Byrd Institute, and plans to support others with first rights of refusal on technologies for treating terminal diseases.

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

This medical shortfall puts a spotlight on an urgent need for development of new therapies capable of treating the estimated more than 45 million people worldwide suffering from dementia today - 5.3 million in North America, 7.5 million in Western Europe, and 3.6 million in Asia-Pacific - a number expected to increase to more than 130 million by 2050. Alzheimer's is the most common cause of dementia, estimated to be associated with some 60 to 70 percent of cases. An additional estimated 1.4 million patients in the U.S. suffer from Lewy body dementia. The potential marketplace for a commercialized therapy or treatment would be tremendously significant with large financial support available from numerous national and international pharmaceutical companies and various governments and worldwide agencies.

#### Manufacturing

We do not have any in-house manufacturing capabilities. The Company intends to outsource the manufacturing of its products to third party contractors, with special capabilities to manufacture chemical drugs and biologic drug candidates for submission and clinical testing under FDA guidelines. There are several sources of manufacturing available once a therapy or treatment can achieve Stage 3 study as identified in a publication by Pharma.org (<u>http://www.phrma.org/sites/default/files/Alzheimer's%202013.pdf</u> released in 2013.

#### **Distribution & Marketing**

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



## **Government Regulation**

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

# Human Health Product Regulation in the U.S.

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

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

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

#### Marketing Approval

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

- nonclinical laboratory and, at times, animal tests;
- submission of an Investigational New Drug ("IND") application 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 Biologics License Application ("BLA"), which must occur before a drug can be marketed or sold.

We will need to successfully complete extensive additional clinical trials in order to be in a position to submit a BLA 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 approval for human health products, human clinical trials are typically conducted in phases that may overlap.

3	0	_

• *Phase I.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

*Phase II.* This phase involves trials in a limited subject population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase II studies may be sub-categorized to Phase IIa studies which are smaller, pilot studies to evaluate limited drug exposure and efficacy signals, and Phase IIb studies which are larger studies testing more rigorously both safety and efficacy.

• Phase III. This phase involves trials undertaken to further evaluate dosage, clinical efficacy and safety in an expanded subject population, often at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

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

# **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 BLA submission requires a substantial user fee payment unless a waiver or exemption applies (such as with the Orphan Drug Designation discussed below). The BLA submission fee currently exceeds \$1,958,000, and the manufacturer and/or sponsor under an approved BLA are also subject to annual product and establishment user fees, currently exceeding \$98,000 per product and \$526,000 per establishment. These fees are typically increased annually. The BLA includes all relevant data available from pertinent non-clinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

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

Based on pivotal Phase III trial results submitted in a 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 a 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 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.

- 40 -

Before approving a 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 a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that any of the application, manufacturing process or manufacturing facilities is not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that if the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the 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 several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

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

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy ("*REMS*") from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA submission. The need for a REMS is determined as part of the review of the 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 BLA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

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

## Disclosure of Clinical Trial Information

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



# The Drug Price Competition and Patent Term Restoration Act

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

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

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

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

# FDA Post-Approval Requirements

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

# Patient Protection and Affordable Care Act

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

# Human Health Product Regulation in the European Union

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



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

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

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

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

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a Marketing Authorization Application ("MAA") by the EMA is 210 days, though the date count stops whenever the Committee for Medicinal Products for Human Use ("CHMP") asks the applicant for additional written or oral information, with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, as when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: (i) the seriousness of the disease to be treated; (ii) the absence of an appropriate alternative therapeutic approach; and (iii) anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter. We plan to submit an application for marketing authorization in the United States for CAO22W in 2017.

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

- 43 -

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

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

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

# Human Health Product Regulation in the Rest of World

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

#### **Other Regulatory Considerations**

#### Labeling, Marketing and Promotion

Once a 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 BLA or 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 BLA supplements as it does in reviewing NDAs.

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



## Anti-Kickback and False Claims Laws

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

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

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

# Other Health Care Laws and Compliance Requirements

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

- 45 -

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

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 nine people over the age of 65 having the disease. The prevalence of the disease is approximately 5.2 million individuals in the US. On the other hand, the incidence (or rate at which new cases of disease develop) is age dependent with approximately 53 new cases per 1,000 people age 65 to 74, 170 new cases per 1,000 people age 65 to 74, 170 new cases per 1,000 people age 75 to 84, and 231 new cases per 1,000 people age 85 and older, with 454,000 new cases occurring in 2010 [Alzheimer's Association, 2013 Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia, Volume 9, Issue 2]. Alzheimer's is also the sixth leading cause of death across all ages in the United States [AA2013: 113], and its prevalence is expected to quadruple by 2050. It is estimated that the cost of caring for people with Alzheimer's and other dementia's will increase from an estimated \$203 billion in 2013 to a projected \$1.2 trillion per year by 2050 with Medicare and Medicaid covering approximately 70% of such costs.

The cause and progression of Alzheimer's disease are not well understood. As of 2012, more than 1,000 clinical trials have been or are being conducted to find ways to treat the disease, but it is unknown if any of the tested treatments will work.

According to the Alzheimer's Foundation of America, it is widely accepted that with the increasing trend towards a longer lifespan coupled with the baby-boomer population approaching retirement, the incidence of Alzheimer's is likely to double in the next 20 years. The exponential increase in the expected number of patients presenting with Alzheimer's not only represents a major area of unmet medical need, but it also represents a significant market opportunity for diagnostics for this disease. Alzheimer's biomarker sales are currently at 1.5 billion USD, but are expected to double within the next 5 years (BCC research 2013).

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

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

# **Intellectual Property**

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret or is protected by confidentiality agreements. Accordingly, patents or other proprietary rights are an essential element of our business.

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

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



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

#### Competition

#### General

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.

## Diagnostics for Alzheimer's Disease

# Cerebrospinal Fluid (CSF)

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

#### Positron Emission Tomography (PET)

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

#### Magneto encephalography (MEG)

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

## Magnetic Resonance Imaging (MRI)

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



#### Cognition

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

# Employees

As of the date of this Offering Circular, we have no full-time employees. The services of the two officers and Chairman of Alzamend Neuro are provided pursuant to the terms of a management services agreement (the "MSA") entered into with Avalanche International, Corp. ("Avalanche"), a related party, on May 1, 2016. Avalanche provides management, consulting and financial services to Alzamend. Such services include advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the MSA, as amended, is for the period May 1, 2016 to December 31, 2016 and may be extended by written agreement. Avalanche receives \$40,000 per month for its services. As opposed to directly compensating our two officers and the chairman of our board of directors, we intend to extend the term of the MSA through 2017. From time to time, we engage consultants on an as-needed basis to supplement existing staff.

## **Corporate Information**

Our mailing address is Alzamend Neuro, Inc., 50 W. Broadway, 3rd Floor, Salt Lake City, UT 84101 and our telephone number is (949) 346-5822. Our website address is <u>www.alzamend.com</u>. The information contained therein or accessible thereby shall not be deemed to be incorporated into this Offering Circular.

- 48 -

# **DESCRIPTION OF PROPERTY**

The Company currently does not maintain an office.

# DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information regarding our executive officers, directors and significant employees, including their ages as of August 2016:

Name	Age	Position
Philip E. Mansour	48	President, Chief Executive Officer & Director
Milton C. Ault, III	46	Chairman & Director
William B. Horne	48	Chief Financial Officer & Director

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

Philip E. Mansour. Mr. Mansour has been retained to establish the Company, Board of Directors, the scientific advisory board, hire and contract with all appropriate FDA consulting firms, as well as establish and negotiate all relationships with the scientific and academic community. Since October 2008, Mr. Mansour has been the full-time principal of PMC Solutions, LLC, specializing in consulting to companies on issues of operational management, strategic planning, marketing business development and disruptive technology. Additionally, Mr. Mansour has provided executive coaching services. Mr. Mansour clients during this period and corresponding roles include: President and Chief Executive Officer of Avalanche International Corp (OTC: AVLP), since May 2014. Mr. Mansour worked as the Chief Operational Officer with the RXtra Solutions organization. The organization was a privately owned set of health care development companies which had footprints in the company focused on At Home Infertility treatment. His prior experience includes leading the research and development for some prominent educational technology companies for more than 2 decades and leading multi-million-dollar government grants with leading universities. His entrepreneurial and significant corporate experience is expected to benefit the Company, including, but not limited to, through establishing its infrastructure and guiding its progression through its projected growth

Milton C. Ault, III. Mr. Ault is a seasoned business professional and entrepreneur that has spent more than twenty-seven years identifying value in various financial markets including equities, fixed income, commodities, and real estate. Mr. Ault has served as Chairman of Avalanche International Corp since September 2014. Since January, 2011 Mr. Ault has been the Vice President of Business Development for MCKEA Holdings, LLC, a private hedge fund. Through this position Mr. Ault has consulted for a few publicly traded and privately-held companies, providing each of them the benefit of his diversified experience, that range from development stage to seasoned businesses. He was the President, Chief Executive Officer, Director and Chairman of the Board of Zealous, Inc. from August 2007 until June 4, 2010 and again from February 2011 through May 1, 2011. Mr. Ault was a registered representative at Strome Securities, LP, from July 1998 until December 2005, where he was involved in portfolio management and worked on several activism campaigns including Taco Cabana, Jack In The Box (formerly Foodmaker), and 21st Century Holdings Co. Mr. Ault was elected to the board of directors of Patient Safety Technologies, Inc. (OTCBB:PSTX, OTCQB:PSTX) ("PST") in July 2004, and became its Chairman and Chief Executive Officer in October 2004 serving until January 2006, and again from July 2006 to January 2007. Stryker Corporation (NYSE:SYK) acquired PST at the beginning of 2014 in a deal valued at approximately one hundred twenty million dollars (\$120,000,000). PST's wholly-owned operating subsidiary, SurgiCount Medical, Inc., is the company that developed the Safety-Sponge® System; a bar coding technology for inventory control that aims to detect and prevent the incidence of foreign objects left in the body after surgery.

William B. Horne. Mr. Horne has served as the Chief Financial Officer of Avalanche International Corp (OTC: AVLP) since June 2016. Mr. Horne has also served as the Chief Financial Officer of Targeted Medical Pharma, Inc. (OTC: TRGM) since August 2013. Mr. Horne previously held the position of Chief Financial Officer in various companies in the healthcare and high-tech field, including OptimisCorp, from January 2008 to May 2013, a privately held, diversified healthcare technology company located in Los Angeles, California. Mr. Horne served as the Chief Financial Officer of Patient Safety Technologies, Inc. (OTCBB: PSTX, OTCQB:PSTX), a medical device company located in Irvine, California, from June 2005 to October 2008 and as the interim Chief Executive Officer from January 2007 to April 2008. In his dual role at Patient Safety Technologies, Mr. Horne was directly responsible for structuring the divestiture of non-core assets, capital financings and debt restructuring. Mr. Horne held the position of Managing Member & Chief Financial Officer of Alaska Wireless Communications, LLC, a privately held, advanced cellular communications company, from its inception in May 2002 until November 2007. Mr. Horne was responsible for negotiating the sale of Alaska Wireless to General Communication Inc. (NASDAQ: GNCMA). From November 1996 to December 2001, Mr. Horne held the position of Chief Financial Officer of The Phoenix Partners, a venture capital limited partnership located in Seattle, Washington. Mr. Horne has also held supervisory positions at Price Waterhouse, LLP and has a Bachelor of Arts Magna Cum Laude in Accounting from Seattle University.

### **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. Each of the Board committees, when established, will also provide risk oversight in respect of its areas of concentration and reports material risks to the board for further consideration.

## Term of Office

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

#### **Director Independence**

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

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

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

## **Family Relationships**

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



#### **Involvement in Certain Legal Proceedings**

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

- · been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general
  partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.
  - 1. Mr. Ault held series 7, 24, and 63 licenses and managed four domestic hedge funds and one bond fund from 1998 through 2008. On April 26, 2012, as a result from an investigation by FINRA involving activities during 2008, Mr. Ault agreed to a settlement with FINRA in which he did not admit to any liability or violation of any laws or regulatory rules and that included restitution and a suspension from association with a FINRA member firm for a period of 2 years. As part of that settlement, Mr. Ault agreed that he would make restitution to certain investors. Mr. Ault did not within the prescribed time period make a restitution payment to certain of the investors as he was unable to locate all of them, nor did he forward the undistributed restitution in the state where the investor was known to have resided, as directed by FINRA.
  - 2. Mr. Ault was CEO, President and Chairman of Zealous Holdings, Inc. that filed for bankruptcy protection under Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code") on February 20, 2009, in the U.S. Bankruptcy Court, Central District of California. This Chapter 11 filing was subsequently converted to a Chapter 7 filing by order of the Bankruptcy Court. Zealous Holdings, Inc. was not an entity that was entitled to a discharge under the bankruptcy code. As such Zealous Holdings, Inc. did not receive a discharge. Ultimately, Zealous Holdings, Inc. ceased doing business and was permanently closed.
  - 3. Mr. Ault filed for bankruptcy protection under Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code") on December 8, 2009, in the U.S. Bankruptcy Court, Central District of California. This Chapter 13 filing was subsequently converted to a Chapter 7 filing by order of the Bankruptcy Court and months later, the petition being withdrawn and dismissed without prejudice.



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

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

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

Our Board plans to adopt a written code of business conduct and ethics 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 will post on our website a current copy of the code and all disclosures that are required by law in regard to any amendments to, or waivers from, any provision of the code.

# EXECUTIVE COMPENSATION

The following table represents information regarding the total compensation our executive officers and director of the Company as of April 30, 2016:

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

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

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

## **Transactions with Related Persons**

The services of the two officers and Chairman of Alzamend Neuro are provided pursuant to the terms of a management services agreement (the "MSA") entered into with Avalanche International, Corp. ("Avalanche"), a related party, on May 1, 2016. Avalanche provides management, consulting and financial services to Alzamend. Such services include advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the MSA, as amended, is for the period May 1, 2016 to December 31, 2016 and may be extended by written agreement. As opposed to directly compensating our two officers and the chairman of our board of directors, we intend to extend the MSA through 2017. Avalanche receives \$40,000 per month for its services.

On April 1, 2016, the Company entered into a subscription agreement with MCKEA Holdings, LLC ("MCKEA"). The Company issued and sold to MCKEA 1,000,000 shares of Series A Preferred Shares that are convertible into 80,000,000 shares of Common Stock that carry the voting power of 200,000,000 shares of common stock. Kristine L. Ault, the wife of Milton C. Ault III, Chairman of the Company's Board, is the manager and owner of MCKEA. The issuance resulted in aggregate gross proceeds to the Company of \$8,000, of which \$5,000 was received in April 2016 and \$3,000 has not been received as of the date these financial statements were issued and recorded as a subscription receivable by reducing stockholders' equity.

To the best of our knowledge, from inception to our initial fiscal year end on April 30, 2016, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds \$120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially own more than 5% of any class of our Common Stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

# PRINCIPAL STOCKHOLDERS

The following table shows the beneficial ownership of our Common Stock as of the date of this Offering Circular held by (i) each person known to us to be the beneficial owner of more than five percent (5%) of any class of our shares; (ii) each director; (iii) each executive officer; and (iv) all directors and executive officers as a group. As August 17, 2016, there were 116,600,000 shares of Common Stock issued and outstanding and 1,360,000 shares of Series A Preferred Stock issued and outstanding.

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

The percentages below are based on fully diluted shares of our Common Stock as of the date of this Offering Circular. Unless otherwise indicated, the principal address of each of the persons below is c/o Alzamend Neuro, Inc., 50 W. Broadway, 3rd Floor, Salt Lake City, UT 84101.

- 53 -

	Number of shares of Common Stock Beneficially		
	Owned as of November 30, 2016	Percentage I Before Offering	Beneficially Owned After Maximum Offering
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Directors and Officers:			
Phil Mansour <sup>(1)</sup>	10,000,000	7.90%	6.54%
Milton C. Ault, III <sup>(2)</sup>	210,000,000	64.30%	59.50%
William B. Horne <sup>(1)</sup>	10,000,000	7.90%	6.54%
All directors and named executive officers as a group (3 persons)	230,000,000	66.36%	61.68%
Greater than 5% Beneficial Owners:			
MCKEA Holdings, LLC <sup>(3)</sup>	200,000,000	63.17%	58.32%
Congregation Chazon Avrohom <sup>(4)</sup>	54,000,000	31.65%	27.42%
RCKJ Trust <sup>(5)</sup>	18,000,000	13.37%	11.19%
University of South Florida Research Foundation, Inc. <sup>(6)</sup>	13,476,316	10.36%	9.38%
William H. Coons III	8,000,000	6.86%	5.60%
JLA Realty, LLC <sup>(7)</sup>	6,000,000	5.15%	4.20

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(1) Consists of options to purchase 10,000,000 shares of Common Stock.

(2) Consists of MCKEA Holdings' 1,000,000 Series A Preferred Shares that are convertible into 80,000,000 shares of Common Stock but carry the voting power of 200,000,000 such shares and options to purchase 10,000,000 shares of Common Stock.

(3) Consists of 1,000,000 Series A Preferred Shares that are convertible into 80,000,000 shares of Common Stock but carry the voting power of 200,000,000 of such shares. The control person of MCKEA Holdings, LLC is Kristine L. Ault, Managing Member, the wife of Mr. Ault.

(4) Consists of 270,000 Series A Preferred Shares that are convertible into 21,600,000 shares of Common Stock but carry the voting power of 54,000,000 of such shares. The control person of the Congregation Chazon Avrohom is Abraham Biderman.

(5) Consists of 90,000 Series A Preferred Shares that are convertible into 7,200,000 shares of Common Stock but carry the voting power of 18,000,000 of such shares. The control person of the RCKJ Trust is Dennis J. Durando.

(6) Consists of shares of Common Stock issuable pursuant to the terms of a license agreement with an effective date of May 1, 2016.

(7) The control person of JLA Realty, LLC is Steven Caspi, Manager.

# **DESCRIPTION OF SECURITIES**

The following is a summary of the rights of our capital stock as provided in our certificate of incorporation and bylaws. For more detailed information, please see our certificate of incorporation and bylaws, which have been filed as exhibits to the Offering Statement of which this Offering Circular is a part.

#### General

The Company is authorized to issue two classes of stock. The total number of shares of stock which the Company is authorized to issue is three hundred and ten million (310,000,000) shares, consisting of three hundred million (300,000,000) shares of Common Stock, \$0.0001 par value and ten million (10,000,000) shares of preferred stock, \$0.0001 par value (the "Preferred Stock").

#### **Common Stock**

As of the date of this Offering Circular, the Company had 116,600,000 shares of Common Stock issued and outstanding.

#### Voting

The holders of the Common Stock are entitled to one vote for each share held at all meetings of shareholders (and written actions in lieu of meeting). There shall be no cumulative voting. The holders of shares of Common Stock are entitled to dividends when and as declared by the Board from funds legally available therefor, and upon liquidation are entitled to share pro rata in any distribution to holders of Common Stock. There are no preemptive, conversion or redemption privileges, nor sinking fund provisions with respect to the Common Stock.

## **Changes in Authorized Number**

The number of authorized shares of Common Stock may be increased or decreased subject to the Company's legal commitments at any time and from time to time to issue them, by the affirmative vote of the holders of a majority of the stock of the Company entitled to vote.

#### Preferred Stock

The Preferred Stock may be issued from time to time in one or more series. The Board is authorized to fix the number of shares of any series of Preferred Stock and to determine the designation of any such series. The Board is also authorized to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon any wholly unissued series of Preferred Stock and, within the limits and restrictions stated in any resolution or resolutions of the Board originally fixing the number of shares constituting any series, to increase or decrease (but not below the number of shares of such series than outstanding) the number of shares of any such series subsequent to the issue of shares of that series. Currently, 1,360,000 shares of Preferred Stock have been designated as Series A Convertible Preferred Stock, all of which are issued and outstanding.

# Series A Preferred Stock

The Board has designated 1,360,000 shares of its Preferred Stock as "Series A Convertible Preferred Stock" (the "Series A Preferred Shares") and issued all such shares as shown in the table in the section entitled "Security Ownership of Certain Beneficial Owners and Management" above.

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 200 non-cumulative votes per share on all matters presented to our stockholders for action. This right could adversely affect the voting power of the holders of common stock and could have the effect of making it more difficult for a third party to acquire, or could discourage or delay a third party from acquiring, a majority of our outstanding stock. 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 eighty (80) shares of Common Stock for every one (1) Series A Preferred Stock Share. The conversion rate is not subject to anti-dilution adjustments.

### DIVIDEND POLICY

We plan to retain any earnings for the foreseeable future for our operations. We have never paid any dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board and will depend on our financial condition, operating results, capital requirements and such other factors as our Board deems relevant.

# PLAN OF DISTRIBUTION

The shares are being offered by us on a best-efforts basis by our officers, directors and employees, with the assistance of independent consultants, and possibly through registered broker-dealers who are members of the Financial Industry Regulatory Authority ("FINRA") and finders. We may pay selling commissions to participating broker-dealers who are members of FINRA for shares sold by them, equal to a percentage of the purchase price of the shares. We may pay finder's fees to persons who refer investors to us. We may also pay consulting fees to consultants who assist us with the offering, based on invoices submitted by them for advisory services rendered. Consulting compensation, finder's fees and brokerage commissions may be paid in cash, common stock or warrants to purchase our common stock. We may also issue shares and grant stock options or warrants to purchase our common stock to broker-dealers for sales of shares attributable to them, and to finders and consultants, and reimburse them for due diligence and marketing costs on an accountable or non-accountable basis. We have not entered into selling agreements with any broker-dealers to date, though we may engage a FINRA registered broker-dealer firm for offering administrative services. Participating broker-dealers, if any, and others may be indemnified by us with respect to this offering and the disclosures made in this Offering Circular.

# ADDITIONAL INFORMATION ABOUT THE OFFERING

#### **Investment Limitations**

Generally, no sale may be made to you in this offering if the aggregate purchase price you pay is more than 10% of the greater of your annual income or net worth (please see below on how to calculate your net worth). Different rules apply to accredited investors and non-natural persons. Before making any representation that your investment does not exceed applicable thresholds, we encourage you to review Rule 251(d)(2)(i)(C) of Regulation A. For general information on investing, we encourage you to refer to <u>www.investor.gov</u>.

Because this is a Tier 2, Regulation A offering, most investors must comply with the 10% limitation on investment in the offering. The only investor in this offering exempt from this limitation is an "accredited investor" as defined under Rule 501 of Regulation D under the Securities Act (an "Accredited Investor"). If you meet one of the following tests you should qualify as an Accredited Investor:



- (i) You are a natural person who has had individual income in excess of \$200,000 in each of the two most recent years, or joint income with your spouse in excess of \$300,000 in each of these years, and have a reasonable expectation of reaching the same income level in the current year;
- (ii) You are a natural person and your individual net worth, or joint net worth with your spouse, exceeds \$1,000,000 at the time you purchase Shares (please see below on how to calculate your net worth);
- (iii) You are an executive officer or general partner of the issuer or a manager or executive officer of the general partner of the issuer;
- (iv) You are an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, or the Code, a corporation, a Massachusetts or similar business trust or a partnership, not formed for the specific purpose of acquiring the Shares, with total assets in excess of \$5,000,000;
- (v) You are a bank or a savings and loan association or other institution as defined in the Securities Act, a broker or dealer registered pursuant to Section 15 of the Exchange Act, an insurance company as defined by the Securities Act, an investment company registered under the Investment Company Act of 1940 (the "Investment Company Act"), or a business development company as defined in that act, any Small Business Investment Company licensed by the Small Business Investment Act of 1958 or a private business development company as defined in the Investment Advisers Act of 1940;
- (vi) You are an entity (including an Individual Retirement Account trust) in which each equity owner is an accredited investor;
- (vii) You are a trust with total assets in excess of \$5,000,000, your purchase of Shares is directed by a person who either alone or with his purchaser representative(s) (as defined in Regulation D promulgated under the Securities Act) has such knowledge and experience in financial and business matters that he is capable of evaluating the merits and risks of the prospective investment, and you were not formed for the specific purpose of investing in the Shares; or
- (viii) You are a plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has assets in excess of \$5,000,000.

#### **Offering Period and Expiration Date**

This offering will start on or immediately prior to the date on which the SEC initially qualifies this Offering Statement (the "Qualification Date") and will terminate on the Termination Date.

## **Procedures for Subscribing**

If you decide to subscribe for Shares in this offering, you should:

Go to www.AlzamendRegA.com, click on the "Reserve Shares" button and follow the procedures as described.

- 1. Electronically receive, review, execute and deliver to us a subscription agreement; and
- Deliver funds directly by wire or electronic funds transfer via ACH to the specified account maintained by Transfer Online, Inc., the official Escrow Agent for this Offering, or mail payment in the form of check, money order or cashier's check directly to Transfer Online, Inc. FBO Alzamend Neuro, Inc. 512 SE Salmon Street, Portland, OR 97214.

Any potential investor will have ample time to review the subscription agreement, along with their counsel, prior to making any final investment decision. We shall only deliver such subscription agreement upon request after a potential investor has had ample opportunity to review this Offering Circular.

*Right to Reject Subscriptions.* After we receive your complete, executed subscription agreement and the funds required under the subscription agreement have been transferred to the escrow account, we have the right to review and accept or reject your subscription in whole or in part, for any reason or for no reason. We will return all monies from rejected subscriptions immediately to you, without interest or deduction.

Acceptance of Subscriptions. Upon our acceptance of a subscription agreement, we will countersign the subscription agreement and issue the shares subscribed at closing. Once you submit the subscription agreement and it is accepted, you may not revoke or change your subscription or request your subscription funds. All accepted subscription agreements are irrevocable.

Under Rule 251 of Regulation A, non-accredited, non-natural investors are subject to the investment limitation and may only invest funds which do not exceed 10% of the greater of the purchaser's revenue or net assets (as of the purchaser's most recent fiscal year end). A non-accredited, natural person may only invest funds which do not exceed 10% of the greater of the purchaser's annual income or net worth (please see below on how to calculate your net worth).

NOTE: For the purposes of calculating your net worth, it is defined as the difference between total assets and total liabilities. This calculation must exclude the value of your primary residence and may exclude any indebtedness secured by your primary residence (up to an amount equal to the value of your primary residence). In the case of fiduciary accounts, net worth and/or income suitability requirements may be satisfied by the beneficiary of the account or by the fiduciary, if the fiduciary directly or indirectly provides funds for the purchase of the Shares.

In order to purchase Shares and prior to the acceptance of any funds from an investor, an investor will be required to represent, to the Company's satisfaction, that he is either an accredited investor or is in compliance with the 10% of net worth or annual income limitation on investment in this offering.

# LEGAL MATTERS

Certain legal matters with respect to the shares of common stock offered hereby will be passed upon by Sichenzia Ross Ference Kesner LLP, New York, NY.

# EXPERTS

The financial statements of the Company appearing elsewhere in this Offering Circular have been included herein in reliance upon the report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, of Marcum LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of that firm as experts in accounting and auditing.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a Regulation A Offering Statement on Form 1-A under the Securities Act of 1993, as amended, with respect to the shares of common stock offered hereby. This Offering Circular, which constitutes a part of the Offering Statement, does not contain all of the information set forth in the Offering Statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the Offering Statement and the exhibits and schedules filed therewith. Statements contained in this Offering Circular regarding the contents of any contract or other document that is filed as an exhibit to the Offering Statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the Offering Statement are not necessarily complete, and each such statement is qualified to file periodic reports, proxy statements, and other information with the SEC pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the SEC's Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, including us, that file electronically with the SEC. The address of this site is <u>www.sec.gov</u>.



# INDEX TO FINANCIAL STATEMENTS ALZAMEND NEURO, INC.

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheet as of April 30, 2016	F-3
Statement of Operations for the period February 26, 2016 (inception) to April 30, 2016	F-4
Statement of Cook Elever for the period Estructure 26, 2016 (in continue) to April 20, 2016	F-5
Statement of Cash Flows for the period February 26, 2016 (inception) to April 30, 2016	F-3
Statement of Changes in Stockholders' Equity (Deficit) for the period February 26, 2016 (inception) to April 30, 2016	F-6
Notes to Financial Statements	F-7 – F-16

_	1	

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Alzamend Neuro, Inc. (the "Company") as of April 30, 2016, and the related statements of operations, changes in stockholders' equity (deficit) and cash flows for the period from February 26, 2016 (inception) to April 30, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Alzamend Neuro, Inc., as of April 30, 2016, and the results of its operations and its cash flows for the period from February 26, 2016 (inception) to April 30, 2016 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 2 to the financial statements, the Company has not generated any revenue, incurred net losses since inception and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Marcum llp Marcum llp New York, NY August 19, 2016

# **Balance Sheet**

	P	April 30, 2016
ASSETS		
CURRENT ASSETS		
Cash	\$	1,141
Subscriptions receivable and prepaid expense		4,473
TOTAL CURRENT ASSETS		5,614
Deferred offering cost		25,000
TOTAL LONG TERM ASSETS		25,000
TOTAL ASSETS	\$	30,614
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable	\$	27,602
Related party payable		3,118
TOTAL CURRENT LIABILITIES		30,720
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Convertible Preferred stock, \$0.0001 par value: 10,000,000 shares authorized;		
Series A Preferred Stock, \$0.0001 stated value per share, 1,360,000 shares designated and 1,000,000 shares issued and outstanding		100
Common stock, \$0.0001 par value: 300,000,000 shares authorized; 46,400,000 shares issued and outstanding		4,640
Additional paid-in capital		9,730
Less: Receivable due from preferred shareholder		(3,000
Accumulated deficit		(11,576)
TOTAL STOCKHOLDERS' DEFICIT		(106
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$</u>	30,614

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

# **Statement of Operations**

February 26, 2016 (Inception) to April 30, 2016

REVENUE	s	
	Ŷ	
OPERATING EXPENSES		
General and administrative expenses		11,576
NET LOSS		(11,576)
Basic and diluted net loss per common share	<u>\$</u>	(0.01)
Basic and diluted weighted average common shares outstanding		2,076,154

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

# Statement of Cash Flows

February 26, 2016 (Inception) to April 30, 2016

Cash flows from operating activities:		
Net loss	\$	(11,576)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation to employees and directors		1,830
Preferred stock issued to shareholder for legal fees paid on Company's behalf		5,000
Changes in operating assets and liabilities:		
Prepaid expense		(938)
Accounts payable		2,602
Net cash used in operating activities		(3,082)
Cash flows from financing activities:		
Proceeds from issuance of common stock		1,105
Advances from related party payable		3,118
Net cash provided by financing activities		4,223
		.,
Net increase in cash		1,141
		,
Cash at beginning of period		_
Cash at end of period	\$	1,141
	φ	1,141
Non each francisc activities:		
Non-cash financing activities:	¢	2 525
Subscription receivable for common stock	\$	3,535
Subscription receivable for preferred stock	\$ \$	3,000
Deferred offering costs included in accounts payable	\$	25,000

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

# Statement of Stockholders' Equity (Deficit)

February 26, 2016 (Inception) to April 30, 2016

		Convertible ed Stock <u>Amou</u>	nt	Commo Shares	 nount	d-In pital	due Pref	ivable from erred holder	umulated Deficit	 Total
BALANCES, February 26, 2016	—	\$	_	—	\$ _	\$ _	\$	—	\$ _	\$ —
Issuance of common stock				46,400,000	4,640					4,640
Issuance of preferred stock	1,000,000		100			7,900		(3,000)		5,000
Stock based compensation	—		—	—	—	1,830		—	—	1,830
Net loss					 	 <u> </u>		_	 (11,576)	 (11,576)
BALANCES, April 30, 2016	1,000,000	\$	100	46,400,000	\$ 4,640	\$ 9,730	\$	(3,000)	\$ (11,576)	\$ (106)

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

#### 1. DESCRIPTION OF BUSINESS

Alzamend Neuro, Inc. (the "Company" or "Alzamend"), is a specialty pharmaceutical company that was formed on February 26, 2016 to develop and commercialize patented intellectual property to prevent, treat and cure Alzheimer's. The first patented solution that Alzamend has licensed to move to commercialization is an immunotherapy vaccine peptide that works both as a treatment and vaccine against Alzheimer's (the "Technology"). The license agreement was entered into on May 1, 2016, subsequent to year end (See Note 10). This therapy works by stimulating the body's own immune system to prevent the formation, and breaks down beta amyloids, which build up in the brain forming a "plaque," and subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's. Immunotherapy is the treatment of disease by inducing, enhancing, or suppressing an immune response.

# 2. LIQUIDITY AND GOING CONCERN

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern. Since inception, the Company has not generated revenues and has incurred losses and reported losses for the period from February 26, 2016 (inception) to April 30, 2016, totaling \$11,576. Further, the Company does not have adequate cash to cover projected operating costs for the next 12 months. These factors raise substantial doubt about the ability of the Company to continue as a going concern. In order to ensure the continued viability of the Company, either future equity or debt financings must be obtained in order to provide a sufficient source of operating capital. To address its liquidity issues, the Company will achieve profitable operations and positive cash flow. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

# 3. SIGNIFICANT ACCOUNTING POLICIES

#### Accounting Estimates

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

#### Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less when purchased to be cash equivalents. The recorded carrying amounts of the Company's cash and cash equivalents approximate their fair value. As of April 30, 2016, the Company had no cash equivalents.

#### Fair Value of Financial Instruments

The Company's financial instruments are accounts payable. The recorded values of payable approximate their fair values based on their short term nature.

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

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

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

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

#### **Income Taxes**

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

The Company recognizes tax liabilities by prescribing a minimum probability threshold that a tax position must meet before a financial statement benefit is recognized and also provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The minimum threshold is defined as a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. To the extent that the final tax outcome of these matters is different than the amount recorded, such differences impact income tax expense in the period in which such determination is made. Interest and penalties, if any, related to accrued liabilities for potential tax assessments are included in income tax expense. Accounting principles generally accepted in the United States ("U.S. GAAP") also requires management to evaluate tax positions taken by the Company and has concluded that as of April 30, 2016, there are no uncertain tax positions taken, or expected to be taken, that would require recognition of a liability that would require disclosure in the financial statements.

# **Stock-Based Compensation**

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

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



#### 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 and warrants 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 as of April 30, 2016:

	April 30,
	2016
Series A convertible preferred stock	80,000,000
Stock options	30,500,000
Warrants	150,000
	110,650,000

### **Recent Accounting Pronouncements**

In August 2014, the FASB issued ASU No. 2014-15 "Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted. The adoption of this standard is not expected to have a material effect on the Company's operating results or financial condition.

In August 2015, the FASB issued ASU No. 2015-15, "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements", which clarifies the guidance set forth in ASU No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs", issued in April 2015. ASU 2015-03 requires that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. ASU 2015-15 provides additional guidance regarding debt issuance costs associated with line-of-credit arrangements, stating that the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred issuance costs ratably over the term of the line-of-credit arrangement. ASU 2015-03 is effective for reporting periods beginning after December 15, 2015. The adoption of ASU 2015-03 and ASU 2015-15 is not expected to have a material effect our financial position, results of operations or cash flows

In March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). ASU 2016-09 aimed at simplifying the accounting for share-based payment transactions. Included in the update are modifications to the accounting for income taxes upon vesting or settlement of awards, employer tax withholding on shared-based compensation, forfeitures, and financial statement presentation of excess tax benefits. We have not yet determined the impact of the update on our financial statements.



# 4. OTHER CURRENT ASSETS

Other current assets are as follows:

	1	ril 30, 016
Subscription receivables	\$	3,535
Prepaid assets		938
Total subscription receivables and prepaid assets	\$	4,473

# 5. 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 period February 26, 2016 (inception) to April 30, 2016, the Company did not recognize any income tax benefit as a result of its net loss. The table below shows the balances for the deferred income tax assets and liabilities as of the date indicated.

	April	April 30, 2016		
Deferred income tax asset:				
Net operating loss carryover	\$	1,367		
Total deferred tax asset		1,367		
Valuation allowance		(1,367)		
Deferred income tax asset, net of allowance	\$			

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

	April 30	April 30, 2016		
Federal and State				
Current	\$	_		
Deferred		(1,367)		
Valuation allowance		1,367		
Income tax provision (benefit)	\$			

During the period February 26, 2016 (inception) to April 30, 2016, the Company did not recognize income tax expense. The Company's effective tax rate was 0% for the period February 26, 2016 (inception) to April 30, 2016. The effective tax rate differed primarily due to the change in the valuation allowance. The reconciliation of income tax attributable to operations computed at the U.S. Federal statutory income tax rate of 15% to income tax expense is as follows:

	Period Ended
	April 30, 2016
Tax benefit at U.S. Federal statutory tax rate	(15.0)%
Increase (decrease) in tax rate resulting from:	
Allowance against deferred tax assets	11.8%
Incentive stock options and other	2.4%
Nondeductible meals & entertainment expense	0.8%
Effective tax rate	0.0%

At April 30, 2016, the Company had total domestic Federal net operating loss carryovers of approximately \$9,115 available to offset future taxable income. Federal net operating loss carryovers ("**NOLs**") expire in 2026. The Company has not filed its 2016 Federal income tax return. The Company will not be able to utilize these carryovers until the related tax returns are filed. In accordance with Section 382 of the Internal Revenue Code, deductibility of the Company's NOLs may be subject to an annual limitation in the event of a change of control as defined under the regulations.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax assets, projected future taxable income and tax planning strategies in making this assessment. After consideration of all of the information available and due to the substantial doubt related to the Company's ability to continue as a going concern and utilize its deferred tax assets, the Company recorded a full valuation allowance of the deferred tax asset. For the period from inception through April 30, 2016 the valuation allowance has increased by \$1,367.

The 2016 tax year 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.

## 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 fifty million (50,000,000) shares of the Company's common stock to be offered to the Company's directors, officers, employees, and consultants. Options granted under the Plan have an exercise price equal to or greater than the fair value of the underlying common stock at the date of grant and become exercisable based on a vesting schedule determined at the date of grant. The options expire between 5 and 10 years from the date of grant. Restricted stock awards granted under the Plan are subject to a vesting period determined at the date of grant.

During the period February 26, 2016 (inception) to April 30, 2016, the Company had stock-based compensation expense of \$1,830, related to issuances from the Plan to the Company's employees and directors, included in reported net loss.

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 we settle these obligations by issuing shares of our common stock from our authorized shares instead of settling such obligations with cash payments.

A summary of stock option activity for the period February 26, 2016 (inception) to April 30, 2016, is presented below:

		Outstanding Options					
	Shares Available for Grant	Number of Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)		Aggregate Intrinsic Value
February 26, 2012	_	_					
Adoption of 2016 SIP	50,000,000	_					
Grants	(30,500,000)	30,500,000	\$	0.0001			
April 30, 2016	19,500,000	30,500,000	\$	0.0001	10.00	\$	—

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (i.e., the difference between our closing stock 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 period February 26, 2016 (inception) to April 30, 2016.

The Company utilized the Black-Scholes option pricing model and the assumptions used for the period February 26, 2016 (inception) to April 30, 2016, are as follows:

	1 Ended 30, 2016
Weighted average risk free interest rate	1.28%
Weighted average life (in years)	5.0
Volatility	71%
Expected dividend yield	0%
Weighted average grant-date fair value per share of options granted	\$ 0.00006

A summary of the changes in the Company's nonvested options during the period February 26, 2016 (inception) to April 30, 2016, is as follows:

	Number of Non-vested Options	Weighted Average Fair Value at Grant Date	Intrinsic Value
Non-vested at February 26, 2016		_	_
Granted from inception to April 30, 2016	30,500,000	\$ 0.0001	—
Forfeited from inception to April 30, 2016	—	—	—
Vested from inception to April 30, 2016	30,500,000	\$ 0.0001	—
Non-vested at April 30, 2016		_	_

As of April 30, 2016, there were no unvested stock options and accordingly no unrecognized compensation cost related to unvested stock options.

# 7. WARRANTS

On April 16, 2016, the Company issued a total of 150,000 warrants, at an exercise price of \$0.001 per share and vest quarterly, pursuant to a consulting agreement for investor relations services. At the time of issuance, the exercise price of the warrant significantly exceeded the fair value of the Company's common stock resulting in a de minimis fair value attributed to the warrant. The Company utilized the Black-Scholes option pricing model and the assumptions used for each period are as follows:

	Period Ended April 30, 2016
Weighted average risk free interest rate	0.92%
Weighted average life (in years)	3.0
Volatility	71%
Expected dividend yield	0%
Weighted average grant-date fair value per share of options granted	\$ 0.00

The following table summarizes information about common stock warrants outstanding at April 30, 2016:

	Outstanding					Exercisable		
		Weighted						
		Average		Weighted			Weighted	
		Remaining		Average			Average	
Exercise	Number	Contractual		Exercise	Number		Exercise	
Price	Outstanding	Life (Years)		Price	Exercisable		Price	
\$ 0.001	150,000	2.96	\$	0.001	150,000	\$	0.001	

# 8. RELATED PARTY TRANSACTIONS

#### Equity Transactions

As of April 30, 2016, the Company had sold 1,000,000 shares of Series A Convertible Preferred Stock to MCKEA Holdings, LLC ("MCKEA"), a related party (See Note 9).

On May 1, 2016, the Company entered into a Management Services Agreement with a related party, Avalanche International Corp. ("Avalanche") (See Note 10).

# 9. EQUITY TRANSACTIONS

# Series A Preferred Stock

The Board of Directors has designated 1,360,000 shares of its Preferred Stock as "Series A Convertible Preferred Stock" (the "Series A Preferred Shares"). The Series A Preferred Shares convey no dividend rights except as may be declared by the Board in its sole and absolute discretion, out of funds legally available for that purpose. Holders of Series A Preferred Shares are entitled to 200 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:



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

- 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 eighty (80) shares of Common Stock for every one (1) Series A Preferred Share. The conversion rate is not subject to anti-dilution adjustments.

### Common Stock

During April 2016, the Company entered into subscription agreements with multiple investors. The Company issued and sold to these investors 46,400,000 shares of its common stock at \$.0001 per share. The issuance resulted in aggregate gross proceeds to the Company of \$4,640, of which \$1,105 was received in April 2016 and the remainder of \$3,535 was received in May 2016 and recorded as an asset on the balance sheet.

On April 1, 2016, the Company entered into a subscription agreement with MCKEA Holdings, LLC ("MCKEA"). The Company issued and sold to MCKEA 1,000,000 shares of Series A Preferred Shares that are convertible into 80,000,000 shares of Common Stock that carry the voting power of 200,000,000 shares of common stock. Kristine L. Ault, the wife of Milton C. Ault III, Chairman of the Company's Board of Directors, is the manager and owner of MCKEA. The issuance resulted in aggregate gross proceeds to the Company of \$8,000, of which \$5,000 was received in April 2016 and \$3,000 has not been received as of the date these financial statements were issued and recorded as a subscription receivable by reducing stockholders' equity.

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

### **10. SUBSEQUENT EVENTS**

#### Agreements

On May 1, 2016, the Company entered into a Management Services Agreement with Avalanche International Corp. ("Avalanche"), a related party. The Company's officers and directors are also officers and directors of Avalanche. Further, MCKEA is the majority member of Philou Ventures, LLC, which is the controlling shareholder of Avalanche. Pursuant to the terms of the Management Services Agreement, Avalanche shall provide management, consulting and financial services to Alzamend. Such services shall include advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the Management Services Agreement is for the period May 1, 2016 December 31, 2016 and may be extended by written agreement. Avalanche shall receive \$40,000 per month for its services.



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

Effective May 1, 2016, the Company entered into a one-year Consulting Agreement with Hallmark Investments, LLC. The terms of the Consulting Agreement provide for \$120,000 in payments to Hallmark for strategic advisory services related to the operations of the Company.

On May 1, 2016, the Company entered into a Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., a nonstock, nonprofit Florida corporation ("Licensor") and a direct support organization of the University of South Florida ("University") (the "License Agreement"). Licensor granted Licensee a royalty bearing, exclusive worldwide license, limited to the field of Alzheimer's Immunotherapy and Diagnostics, under United States Patent No. 8,188,046, entitled "Amyloid Beta Peptides and Methods of Use", filed April 7, 2009 and granted May 29, 2012.

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

nent	Due Date	Event
50,000	October 1, 2017	IND Filing
50,000	12 months from IND filing date	Upon first dosing of patient in first Phase I Clinical Trial
175,000	12 months from first patient dosed in Phase I	Upon Completion of first Phase I Clinical Trial
500,000	24 months from completion of first Phase I Trial	Upon Completion of first Phase II Clinical Trial
1,000,000	12 months from completion of the first Phase II Clinical Trial	Upon first patient treated in a Phase III Clinical Trial
10,000,000	7 years from the Effective Date of the Agreement	Upon FDA Approval
	50,000 50,000 175,000 500,000 1,000,000	50,000October 1, 201750,00012 months from IND filing date175,00012 months from first patient dosed in Phase I500,00024 months from completion of first Phase I Trial1,000,00012 months from completion of the first Phase II Clinical Trial

None of the milestones were met as of the date these financial statements were issued.

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 Licensee shall be increased upon such issuance. The amount of the increase shall be determined by multiplying the number of shares the 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 plus (ii) the number of shares of common stock which the aggregate consideration for the total number 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 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.

### Common and Preferred 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.



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

On May 30, 2016, the Company's Board of Directors approved an increase in the number of preferred shares designated as Series A Preferred Stock from 1,000,000 shares to 1,360,000 shares.

During May 2016, the Company entered into subscription agreements with multiple investors. The Company issued and sold to these investors 46,700,000 shares of its common stock at \$.0001 per share. The issuance resulted in aggregate gross proceeds to the Company of \$4,670. The Company anticipates payment in full for these shares, of \$4,670, by August 31, 2016 and it has recorded a receivable at May 31, 2016. Through August 4, 2016, \$1,370 of the outstanding receivable has been paid.

On May 30, 2016, the Company entered into subscription agreements for the sale of 360,000 shares of Series A Preferred Stock to two investors at \$0.008/share for an aggregate purchase price of \$2,880. The Company received \$288 in cash and recorded a receivable for \$2,592. The Series A Preferred Stock is convertible into 28,800,000 shares of Common Stock.

On June 23, 2016 and July 6, 2016, the Company entered into subscription agreements with EAV, LLC for the purchase of 500 units at \$1,000 for each unit purchased. Each unit consisted of 23,500 shares of Common Stock. In aggregate, EAV purchased a total of 1,000 units, representing 23,500,000 shares of Common Stock for an aggregate of \$1,000,000, or approximately \$0.0426 per share, pursuant to the terms of a Private Placement Memorandum dated June 3, 2016. Payment for the 1,000 units was received between July 7, 2016 and August 2, 2016. In conjunction with the Private Placement Memorandum, the Company incurred \$100,000 in placement fees to Palladium Capital Advisors, LLC, and \$39,885 in legal and filing fees, resulting in net proceeds to the Company of \$860,115.

### JLA Note Agreement

During the period from May 11, 2016 to June 3, 2016, JLA Realty Associates, LLC loaned \$75,000 to the Company. As consideration for the loan, the Company issued JLA Realty a promissory note in the aggregate principal amount of \$75,000 (the "JLA Note"). The JLA Note provides for a loan fee of \$5,000 and is due 60 days from the date of the loan. The JLA Note, including the loan fee, was repaid on July 7, 2016.

F-16

### PART III-EXHIBITS

### Index to Exhibits

Exhibit No.	Exhibit Description
2.1	Certificate of Incorporation**
2.2	Bylaws**
4.1	Form of Subscription Agreement**
6.1	Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., dated May 1, 2016**
6.2	Management Services Agreement, as amended, with Avalanche International Corp., dated May 1, 2016**
8.1	Escrow Agreement, dated May 24, 2016**
11.1	Consent of Marcum LLP*
11.2	Consent of Sichenzia Ross Ference Kesner LLP (included in Exhibit 12.1)**
12.1	Opinion of Sichenzia Ross Ference Kesner LLP**
13.1	Marketing Materials**

\* Filed herewith \*\* Previously filed

### SIGNATURES

Pursuant to the requirements of Regulation A, the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form 1-A and has duly caused this offering statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Salt Lake, State of Utah, on November 30, 2016.

(Exact name of issuer as specified in its charter):

Alzamend Neuro, Inc.

By (Signature and Title):

/s/ Philip Mansour Chief Executive Officer (Principal Executive Officer).

This offering statement has been signed by the following persons in the capacities and on the dates indicated.

(Signature):	/s/ William B. Horne			
(Title):	Chief Financial Officer (Principal Financial Officer, Principal Accounting Officer).			
(Date):	November 30, 2016			
SIGNATURES OF DIRECTORS:				
/s/ Philip Mansour Philip Mansour, Chief Executive Officer, Director		November 30, 2016 Date		
/s/ Milton C. Ault, III		November 30, 2016		
Milton C. Ault, III, Chairman		Date		
/s/ William B. Horne		November 30, 2016		
William B. Horne, Chief Financial Officer, Director		Date		

### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Offering Statement of Alzamend Neuro, Inc. on Form 1-A of our report dated August 19, 2016, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audit of the financial statements of Alzamend Neuro, Inc. as of April 30, 2016 and for the period from February 26, 2016 (inception) to April 30, 2016, which report appears in the Offering Circular, which is part of this Offering Statement. We also consent to the reference to our Firm under the heading "Experts" in such Offering Circular.

/s/ Marcum llp Marcum LLP

New York, NY November 30, 2016



Alzamend Neuro, Inc. 50 W. Broadway, 3rd Floor Salt Lake City, UT 84101

### Re: <u>Alzamend Neuro, Inc. - Validity of Issuance of Shares</u>

Ladies and Gentlemen:

We have acted as special counsel to Alzamend Neuro, Inc., a Delaware corporation (the "**Company**"), in connection with the Company's Offering Statement on Form 1-A (the "**Offering Statement**"), relating to the application for exemption from registration under Section 3(b) of the Securities Act of 1933, as amended (the '**Securities Act**"), and Regulation A promulgated thereunder, of 25,000,000 shares of common stock, par value \$0.0001 per share (the "**Shares**").

In connection with rendering the opinion set forth herein, we have examined and relied on originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates of public officials, certificates of officers or other representatives of the Company and others and such other documents, certificates and records as we have deemed necessary or appropriate as a basis for the opinions set forth in this letter.

In our examination, we have assumed the legal capacity of all natural persons, the genuineness of all signatures (including endorsements), the authenticity of all documents submitted to us as originals and the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies and the authenticity of the originals of such documents. As to any facts material to the opinions expressed herein which we have not independently established or verified, we have relied upon statements and representations of the Company and its officers and other representatives and of public officials and others.

Based upon and subject to the foregoing, we are of the opinion that upon issuance, the Shares will be validly issued and fully paid and nonassessable.

For the purposes of this opinion, we are assuming that the appropriate certificates are duly filed and recorded in every jurisdiction in which such filing and recordation is required in accordance with the laws of such jurisdictions. We express no opinion herein as to any laws other than the General Corporation Law of the State of Delaware.

We hereby consent to the filing of this opinion with the Securities and Exchange Commission (the 'Commission") as an exhibit to the Offering Statement. We also consent to the reference to our firm in the Offering Statement. We do not admit in providing such consent that we are included in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

Respectfully submitted,

/s/ Sichenzia Ross Ference Kesner LLP Sichenzia Ross Ference Kesner LLP

61 Broadway | New York, NY | 10006 T (212) 930 9700 | F (212) 930 9725 | WWW.SRFKLLP.COM November 14, 2016

## Biotech IPO - Alzheimer's Vaccine

Ad www.alzamendrega.com "Testing The Waters" for an IPO, Learn more.

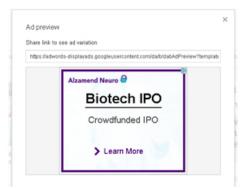
### Biotech IPO - Alzheimer's Vaccine

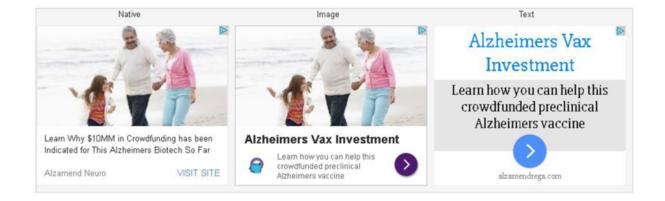
Ad www.alzamendrega.com

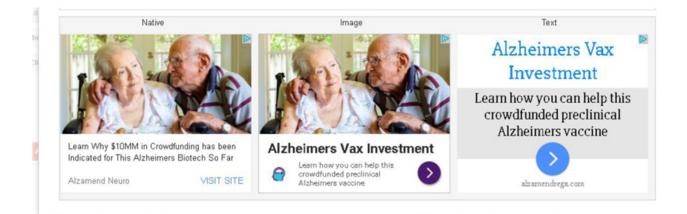
"Testing The Waters" for an IPO, Learn more.

Biotech IPO - Alzheimer's Vaccine Ad www.alzamendrega.com "Testing The Waters" to Gauge Market Demand from Potential Investors

### Display Ad Images.

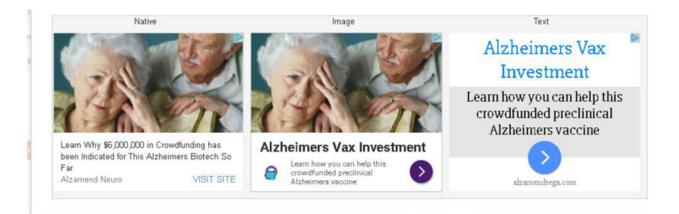














### Committed to Prevention, Treatment and Cure, of Alzheimer's

Alzamend Neuro is currently working to move a patented mutant peptide for use as an immunotherapeutic treatment and vaccine out of the research and preclinical stage at the University of South Florida Byrd Institute and into a path toward commercialization.

Simultaneously, if it goes forward with the RegA+ offering, Alzamend intends to commit a significant portion of the funds raised directly to fund ongoing research projects with National Partners like the University of South Florida Byrd Institute to secure future intellectual property license rights for commercialization.





ALZAMEND NEURO

NEWSLETTER

RESERVE

5444 people who have made their reservation in this mini IPO.

## ALZAMEND NEURO is testing the waters to gauge market demand from potential investors.

"Alzamend Neuro is committed to supporting the full product development life cycle of treatment and cures for Alzheimer's believing that strong support of research is the foundation for true innovation. Providing current hope though the commercialization of existing patented intellectual property and know-how while simultaneously funding Future Hope through advance research."

- Phil Mansour, CEO Alzamend Neuro

# SHARE THIS OPPORTUNITY



**16 Million** People will have Alzheimer's by 2050 if a

cure is not found

## 1-in-9

Americans over 65 have Alzheimer's Disease



Americans Alzheimer's

5.3 Mi



## WHAT IS ALZHEIMER'S DISEASE?

## **Overview of RegA+**

In the past only wealthy investors, venture capitalist, and private equity firms have had the opportunity to invest via special securities in private to public transactions. That has changed as of June 2015. In light of this change we are considering allowing existing customers and the general public to participate in the growth of Alzamend. If you are interested in finding out more or participating in this going public transaction, indicate interest to reserve your shares in this mini-IPO.





## **Our Story**

"I vividly remember visiting my grandmother one day and not only did she not recognize me, but she feared me as though I were a stranger. Over the years as more than six other family members became affected by the disease, I studied and learned more about its devastating nature. I felt compelled to take action." – Chairman Milton "Todd" Ault III

Through his personal experience and diligent study of the status of treatments, and the landscape of medical technology, Mr. Ault, chose the Byrd Institute and their intellectual property, and formed Alzamend as his starting point to make a difference. Twenty-Five years of experience on Wall Street at buying and selling companies as an activist, and his relentless passion for business and technology has culminated in a commitment to depart from the traditional while forging ahead with a disruptive path to financing the commercialization and the discovery of future solutions.

Mr. Ault was quick to recognize the opportunity to make a difference in routine medical procedures that at times resulted in fatal consequences. He founded and launched Patient Safety Technologies Inc., believing in the impact of bar-coded sponge technology, long before anyone else would support it, and it is has now become the standard of care in operating rooms around the world, saving countless lives and subsequent lawsuits annually.

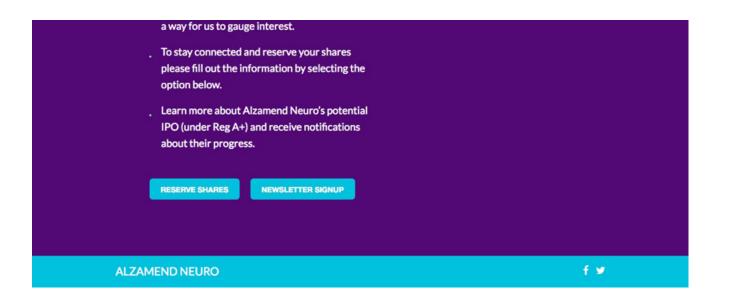
Providing a team of Operational and Financial executives with proven track records, Mr. Ault has made an allstar cast to move this vision forward, without burdening the company with excessive overhead.

## Meet Our Leadership

Phil Mansour CEO/PRESIDENT Prof. Chuanhai Cao (USF/ Byrd Institute) PHD Will Horne CFO

## **Interested?**

This is not a financial commitment. This is simply



## **Phil Mansour**

Mr. Mansour has been retained to establish the Company, Board of Directors, the scientific advisory board, hire and contract with all appropriate FDA consulting firms, as well as establish and negotiate all relationships with the scientific and academic community. Mr. Mansour has led research and development for various prominent educational technology companies for more than 2 decades. He has also consulted with entrepreneurial as well as large organizations focused on disruptive technology and business models in the areas of medical devices, pharmaceuticals, energy and investment. He has led multi-million-dollar government grants with leading universities. His substantial entrepreneurial and corporate experience will benefit the Company, including, but not limited to, establishing its infrastructure, attracting and hiring appropriate leadership, and guiding its progression through its projected growth.

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## Will Horne

Mr. Horne served as the Chief Financial Officer of Targeted Medical Pharma, Inc. (OTCBB: TRGM) since August 2013. Mr. Horne previously held the position of Chief Financial Officer in various companies in the healthcare and high-tech field, including OptimisCorp, from January 2008 to May 2013, a privately held, diversified healthcare technology company located in Los Angeles, California. Mr. Horne served as the Chief Financial Officer of Patient Safety Technologies, Inc. (OTCBB: PSTX), a medical device company located in Irvine, California, from June 2005 to October 2008 and as the interim Chief Executive Officer from January 2007 to April 2008. In his dual role at Patient Safety Technologies, Mr. Horne was directly responsible for structuring the divestiture of non-core assets, capital financings and debt restructuring. Mr. Horne held the position of Managing Member & Chief Financial Officer of Alaska Wireless Communications, LLC, a privately held, advanced cellular communications company, from its inception in May 2002 until November 2007. Mr. Horne was responsible for negotiating the sale of Alaska Wireless to General Communication Inc. (NASDAQ: GNCMA). From November 1996 to December 2001, Mr. Horne held the position of Chief Financial Officer of The Phoenix Partners, a venture capital limited partnership located in Seattle, Washington. Mr. Horne has also held supervisory positions at Price Waterhouse, LLP and has a Bachelor of Arts Magna Cum Laude in Accounting from Seattle University.

### ALZAMEND NEURO

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## Prof. Chuanhai Cao (USF/ Byrd Institute)

Dr. Chuanhai Cao is a Professor at the University of South Florida College of Pharmacy. His lab located on the 4th Floor of the USF Health Byrd Alzheimer's Research Institute located on the USF Main Campus. His research interests are focused on the discovery of therapeutics and vaccinations to neurological diseases, such as Alzheimer's, Parkinsons, Multiple Sclerosis, and ALS among many others.

Read More About Dr. Cao

### Publications

Feb 2016 Transient Micro-needle Insertion into Hippocampus Triggers Neurogenesis and Decreases Amyloid Burden in a Mouse Model of Alzheimer's Disease. Cell Transplant. Jan 2016 Acupuncture-Induced Analgesia: The Role of Microglial Inhibition. Cell Transplant. Dec 2015 Transcription factor Sp1 inhibition, memory, and cytokines in a mouse model of Alzheimer's disease. Am J Neurodegener Dis. Nov 2015 Brain-derived Neurotrophic Factor Signaling Pathway: Modulation by Acupuncture in Telomerase Knockout Mice. Altern. Ther Health Med. Nov 2015 Dendritic and Langerhans cells respond to Aß peptides differently: implication for AD immunotherapy. Oncotarget. Oct 2014 The potential therapeutic effects of THC on Alzheimer's disease. J Alzheimers Dis. Apr 2011 Long-term electromagnetic field treatment enhances brain mitochondrial function of both Alzheimer's transgenic mice and normal mice: a mechanism for electromagnetic field-induced cognitive benefit? Neuroscience. Dec 2009 Caffeine reverses cognitive impairment and decreases brain amyloid- beta levels in aged Alzheimer's disease mice. J Alzheimers Dis. Aug 2008 Mutant amyloid-beta-sensitized dendritic cells as Alzheimer's disease vaccine. J Neuroimmunol.

### ALZAMEND NEURO

Read More About Dr. Cao

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### ALZAMEND NEURO

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RESERVE

### f У NEWSLETTER

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## Interested?

This is not a financial commitment. This is simply a way for us to gauge interest.

- Learn more about Alzamend Neuro's potential fundraiser and receive notifications about their progress.
- To stay connected please complete this information.

INDICATE POTENTIAL AMOUNT							
\$500 - \$1,000	\$1,000 - \$2,500						
\$2,500 - \$5,000	\$5,000 - \$7,500						
\$7,500 - \$10,000	\$10,000 - \$25,000						
\$25,000 - \$50,000	\$50,000 - \$100,000						
\$100,000 - \$500,000	\$500,000+						
AMOUNT UNKNOWN							
FIRST NAME	LAST NAME						
EMAIL	PHONE (OI	PTIONAL)					
I AM AN ACCREDITED INVESTOR			SHORES				
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	will not be accepted. Offers to buy securities cannot be accepted, and no part of the purchase price can be received, until an offering circular on						
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before notice of its acceptance is given after the qualification date of the							
offering circular. No sales of securities will be made or commitment to purchase accepted until qualification of the offering statement by the							
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