



**ALPHA COGNITION INC.**

Management's Discussion and Analysis  
For the year ended December 31, 2023

(Expressed in United States Dollars)

## MANAGEMENT'S DISCUSSION AND ANALYSIS

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This Management's Discussion and Analysis ("MD&A") of Alpha Cognition Inc. ("ACI" or the "Company") provides analysis of the Company's financial results for the year ended December 31, 2023. The following information should be read in conjunction with the accompanying audited financial statements and accompanying notes for the years ended December 31, 2023 and 2022 ("Annual Financial Statements") which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The Board of Directors of the Company have approved the information and disclosures contained in this MD&A. All figures are in United States dollars ("USD") unless otherwise noted. Additional information relating to the Company is available on SEDAR at [www.sedarplus.ca](http://www.sedarplus.ca).

## FORWARD-LOOKING STATEMENTS

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The Company's Annual Financial Statements and this accompanying MD&A contain statements that constitute "forward-looking statements" within the meaning of National Instrument 51-102. Continuous Disclosure Obligations of the Canadian Securities Administrators.

***It is important to note that, unless otherwise indicated, forward-looking statements in this MD&A describe the Company's expectations as at April 3, 2024.***

Forward-looking information is subject to known and unknown risks, uncertainties and other factors that may cause the Company's actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information. The information set forth in this MD&A contains statements concerning future results, future performance, intentions, objectives, plans and expectations that are, or may be deemed to be, "forward-looking statements". These statements concerning possible or assumed future results of operations of the Company are preceded by, followed by or include the words "believes", "expects", "anticipates", "estimates", "intends", "plans", "forecasts", or similar expressions. Forward-looking statements are not guarantees of future performance. These forward-looking statements are based on current expectations that involve certain risks, uncertainties and assumptions. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. These factors should be considered carefully, and readers should not place undue reliance on forward-looking statements. The Company has no intention and undertakes no obligation to update or revise any forward-looking statements, whether written or oral that may be made by or on the Company's behalf, except as may be required by applicable law.

All of the Company's public disclosure filings may be accessed via [www.sedarplus.ca](http://www.sedarplus.ca) and readers are urged to review these materials.

## COMPANY DESCRIPTION

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ACI is the parent company of Alpha Cognition Canada Inc. ("ACI Canada") which is the parent company of Alpha Cognition USA Inc. ("ACI USA"). As of May 1, 2023, the Company's common shares commenced trading on the Canadian Securities Exchange ("CSE") under the symbol "ACOG", previously the Company's shares were traded on the TSX Venture Exchange ("TSX-V") until April 28, 2023, when the Company had them delisted. The Company's shares also trade on the Over-The-Counter Markets ("OTC") under the trading symbol "ACOGF".

The Company is a pre-commercial, biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's disease, for which there are limited or no treatment options. The Company is focused on the development of ALPHA-1062 for the treatment of mild-to-moderate Alzheimer's disease following the recent New Drug Application (the "NDA") submission and acceptance by FDA. The company is now focused on FDA review of the NDA, approval, and subsequent commercial sales of ALPHA-1062 oral tablet formulation. The Company's ALPHA-1062 development program

is primarily focused on clinical and regulatory development, Chemistry, Manufacturing and Control (CMC) development, and commercial readiness. The Company has three additional development programs: ALPHA-1062 in combination with memantine for the treatment of moderate-to-severe Alzheimer's disease, ALPHA-1062 sublingual formulation, ALPHA-1062 intranasal ("ALPHA-1062IN") formulation for the treatment of mild cognitive impairment with mTBI, and ALPHA-0602, ALPHA-0702 & ALPHA-0802, also referred to as 'Progranulin' and 'Progranulin GEM's', for the treatment of neurodegenerative diseases including amyotrophic lateral sclerosis, otherwise known as ALS or Lou Gehrig's disease and spinal muscular atrophy (SMA).

ALPHA-1062, is a patented new innovative product being developed as a next generation acetylcholinesterase inhibitor for the treatment of Alzheimer's disease, with expected minimal gastrointestinal side effects. ALPHA-1062's active metabolite is differentiated from donepezil and rivastigmine in that it binds neuronal nicotinic receptors, most notably the alpha-7 subtype, which is known to have a positive effect on cognition. ALPHA-1062 is in development in combination with memantine to treat moderate to severe Alzheimer's disease, in development with sublingual formulation for patients suffering from dysphagia, and has been out-licensed to study an intranasal formulation for cognitive impairment with mTBI (otherwise known as concussion).

Preclinical stage assets include ALPHA-0602, ALPHA-0702 & ALPHA-0802 (Progranulin and Progranulin GEM's), which are expressed in several cell types in the central nervous system and in peripheral tissues, promotes cell survival, regulates certain inflammatory processes, and play a significant role in regulating lysosomal function and microglial responses to disease. Its intended use for the treatment of neurodegenerative diseases has been patented by the Company and ALPHA-0602 has been granted an Orphan Drug Designation for the treatment of ALS by the FDA. ALPHA-0702 and ALPHA-0802 are Granulin Epithelin Motifs, ("GEMs"), derived from full length progranulin which have therapeutic potential across multiple neurodegenerative diseases. GEMs have been shown to be important in regulating cell growth, survival, repair, and inflammation. ALPHA-0702 and ALPHA-0802 are designed to deliver this with potentially lower toxicity, and greater therapeutic effect.

### **Business Objectives and Milestones**

The Company's principal business objectives are to: 1) obtain FDA approval for its NDA for ALPHA-1062 in mild-to-moderate Alzheimer's disease. The company has been granted a Prescription Drug User Fee Act (PDUFA) goal date of July 27th, 2024. 2) continue to advance its development and commercialization activities for ALPHA-1062 in mild-to-moderate Alzheimer's disease, including the commercial manufacturing for ALPHA-1062 and 3) pursue the out-licensing of its TBI indication to Alpha Seven, where the TBI indication can be further developed through a complete IND application submission following the completion of an additional toxicity study and formulation work. 2023 was a transformational year as we began the transition from a clinical research focused company advancing toward a pre-commercial entity, following the filing of our New Drug Application for ALPHA-1062 for mild-to-moderate Alzheimer's disease.

In order to meet these business objectives, the Company plans to initiate or complete the following milestones over the coming year:

- *ALPHA-1062 U.S. product approval for treatment of mild-to-moderate Alzheimer's disease — The Company will need to respond to regulatory questions and inquiries from FDA in a satisfactory manner and negotiate the commercial label and approval of the product with FDA, which is anticipated in Q3 2024. If approved, ALPHA-1062 would be the second oral therapy available for Alzheimer's patients in the past decade. The approval would represent a next generation oral treatment for disease that address the cognitive symptoms of Alzheimer's disease. Approval could provide the Company with significant new business opportunities for commercial and/or development partners.*
- *Commercialization — The Company plans to continue its development activities and commercialization preparations around ALPHA-1062. CMC activities may involve continuing to refine and defining manufacturing practices and product specifications to be followed and met to ensure product safety and consistency between batches. This will include further CMC activities specifically to target commercial batches. The Company will also refine its commercialization marketing plan which includes the Long Term Care target market, prioritization of LTC customers, , commercialization positioning, marketing messages, and operational plans.*

- *ALPHA-1062 Intranasal for TBI out-licensing — The Company plans to complete the out-license the TBI asset into Alpha Seven where Alpha Seven plans to raise the additional capital to advance the TBI program. The Company expects to include the following in the TBI out-license agreement with the Alpha Seven: intellectual property specific to TBI, implementation of a data sharing agreement, and supply and comprehensive manufacturing agreements for technology advancements in the product. The Company also intends to utilize its existing management and new consultants experienced in TBI research and development to staff Alpha Seven. Data will be shared from pre-clinical, clinical, and manufacturing work to Alpha Seven to help the company advance the asset.*

The foregoing business objectives will be adjusted based on available funds. The estimated timeframe for achieving the milestones and objectives set out above is subject to the Company's ability to obtain additional financing.

### **Going Concern and Additional Capital Required**

The Company has not generated revenues from its operations to date and as at December 31, 2023, had a deficit of \$63,353,768 (December 31, 2022 - \$49,986,851) which has been primarily financed by equity. The Company had \$1,494,573 in cash and restricted cash and \$2,624,902 in current liabilities (of which \$80,000 is payable from the Company's available restricted cash balance) as of December 31, 2023. The Company's continuing operations, as intended, are highly dependent upon its ability to obtain additional funding and generate cash flows. Management is of the opinion that it does not have sufficient working capital to fully meet the Company's liabilities and commitments as outlined and planned in the following discussion. Management is of the opinion it will need to raise additional capital to cover upcoming planned R&D, commercialization and operating costs. Possible sources of such capital may come from private placements and public offerings of the Company's common shares and funds received from the exercise of warrants and share options. Additionally, the Company will also consider funding that may arise through partnership activities and debt. There is a risk that additional financing will not be available on a timely basis, on terms acceptable, or at all to the Company. These factors indicate the existence of a material uncertainty which causes significant doubt in the ability of the Company to continue as a going concern.

The Company has maintained the cost cutting measures it initiated in the third quarter of 2022 to extend its cash runway and reduce ongoing cash burn. The Company focus has been to streamline R&D programs and has prioritized spend towards the NDA filing and development of ALPHA-1062 in AD. The Company reduced headcount and other operating costs to focus spending on the ALPHA-1062 NDA file and other related development costs. The Company expects to continue to operate under the lower operating burn during the NDA filing and approval period or until further additional capital can be secured. If we are unable to raise adequate funds, we may have to further delay or reduce the scope of or eliminate some or all of our operating and commercialization plans and product development. Any of these actions could have a material adverse effect on our business, results of operations or financial condition.

### **Capital Raising**

During the first quarter of 2023 the Company completed a private placement by issuing 23,747,648 units at a price of CAD\$0.255 for total proceeds of \$4,506,055 (CAD\$6,055,650) with each unit consisting of one Common share and one warrant exercisable at a price of CAD\$0.39 per warrant for a term of 5 years from the closing date ("Q1 2023 PP").

- On February 16, 2023 the Company closed the first tranche of the Q1 2023 PP by issuing 16,795,221 units of the Company for gross proceeds of CAD\$4,282,781.
- On March 16, 2023, the Company closed the second tranche of the Q1 2023 PP by issuing 6,952,427 units of the Company for gross proceeds of CAD\$1,772,869.

In connection with the Q1 2023 PP, Spartan Capital Securities, LLC ("Spartan") received cash compensation of US\$172,480 and was issued 2,129,566 common shares of the Company and 324,642 common share purchase warrants which may be exercised on the same terms as the unit warrants.

On May 30 2023, the Company announced a best efforts private placement offering of up to US\$6,500,000 of units at the initial pricing of US\$0.22 per unit ("Q2 2023 PP"). The aggregate proceeds may be increased by 30% to accommodate any over-allotment. The Company also announced that it entered into an Investment Banking Agreement ("IBA") with Spartan Securities LLC ("Spartan") pursuant to which Spartan will act as agent on a best efforts basis in connection with the Q2 2023 PP. In accordance with the Q2 2023 PP, the Company has agreed to pay Spartan cash commissions of 10% of the gross proceeds, issue Spartan finder's warrants equal to 10% of the number of the warrants issued to investors, in each case excluding investors on the Company's president's list, and pay Spartan a non-accountable expense fee equal to 5% of the gross proceeds of the Q2 2023 PP excluding the president's list.

The Company completed the final closing of the Q2 2023 PP on January 19, 2024, where the gross proceeds of the offering received to closing are US\$8.45 million, which includes shares of the fully subscribed 30% over-allotment.

The following table summarizes the Q2 2023 PP closing activity:

| Date Issued       | Tranche   | # Units Issued at \$0.22 per Share | Gross Proceeds      | # Warrants issued at \$0.31 per Warrant | Cash Commissions Paid <sup>(2)</sup> | Agent Warrants Issued <sup>(1)</sup> | Fair Value of Agent Warrants Issued <sup>(3)</sup> | Warrant Expiry Date |
|-------------------|-----------|------------------------------------|---------------------|-----------------------------------------|--------------------------------------|--------------------------------------|----------------------------------------------------|---------------------|
| August 31, 2023   | Tranche 1 | 6,114,058                          | \$ 1,345,093        | 3,057,025                               | \$ 180,051                           | 272,083                              | \$ 44,292                                          | August 31, 2026     |
| October 16, 2023  | Tranche 2 | 1,596,830                          | \$ 351,303          | 798,414                                 | \$ 5,160                             | 78,181                               | \$ 10,199                                          | October 16, 2026    |
| November 8, 2023  | Tranche 3 | 4,590,903                          | \$ 1,009,999        | 2,295,449                               | \$ 151,500                           | 229,544                              | \$ 24,692                                          | November 8, 2026    |
| December 22, 2023 | Tranche 4 | 9,141,534                          | \$ 2,011,137        | 9,141,534                               | \$ 238,515                           | 722,771                              | \$ 249,965                                         | December 22, 2026   |
| January 19, 2024  | Tranche 5 | 16,965,762                         | \$ 3,732,468        | 16,965,762                              | \$ 342,320                           | 1,037,330                            | TBD                                                | January 19, 2027    |
| <b>Totals</b>     |           | <b>38,409,087</b>                  | <b>\$ 8,450,000</b> | <b>32,258,184</b>                       | <b>\$ 917,546</b>                    | <b>2,339,909</b>                     | <b>\$ 329,148</b>                                  |                     |

(1) Each warrant is exercisable at \$0.31 per warrant.

(2) On November 8, 2023, the Company also paid a consulting fee of US\$160,000 pursuant to the Spartan Consulting Agreement. In January 2024 the Company also paid a consulting fee of US\$320,000 and issued 14,558,285 common shares to Spartan pursuant to a consulting agreement. The Company also paid to certain finders aggregate cash commission of US\$48,858, being 6% of the gross proceeds raised under the offering from investors introduced to the Company by such finders.

(3) TDB – to be determined during the accounting period in which the Warrants were issued.

In May 2023 the Company also agreed to enter into an ongoing consulting services agreement for a three-year term with Spartan. The services include advising and assisting on potential business development transactions, strategic introductions, assisting management with enhancing corporate and shareholder value, and capital raising advice. The Company will pay Spartan a consulting fee in the aggregate amount of \$480,000, payable in three equal installments with each installment being subject to the Company achieving certain business development and capital raising objectives. Spartan will also be entitled to earn and receive additional common shares of the Company such that Spartan will hold 10.6% of the outstanding common shares of the Company determined as at the closing of the offering, inclusive of the 2,129,566 common shares currently held by Spartan. The additional common shares will be issued to Spartan on a rolling basis upon completion of predetermined business development objectives including the closing of certain offering amounts and the completion of material business transactions. As of December 31, 2023, \$160,000 in consulting fees have been paid and no additional common shares had been earned or issued under the consulting services agreement with Spartan. In January 2024, the Company paid the remaining \$320,000 in consulting fees and issued 14,558,285 common shares to Spartan pursuant to the consulting agreement.

## Products and Developments

### ALPHA-1062

ALPHA-1062 is a patented new innovative product. When absorbed through mucosal tissue or ingested it is enzymatically converted to an active moiety that has previously been approved by the FDA and marketed by Janssen, a wholly-owned subsidiary of Johnson & Johnson, as Razadyne (generic name is galantamine) in North America, and as Reminyl in Europe and elsewhere. Patients treated with Razadyne experience gastrointestinal side effects which can limit its effectiveness. ALPHA-1062, a prodrug of galantamine, however

may have reduced gastrointestinal side effects which could allow for faster dosing titration and may facilitate achieving therapeutic dosing levels faster. Drugs that convert from an inert form to an active substance in-situ are referred to as “prodrugs”. At the time the Company licensed the ALPHA-1062 technology, only an intranasal formulation had been developed, and subsequently oral dosage formulations have been developed. The Company believes ALPHA-1062 works in two different ways within the brain, by (1) raising the concentration of an essential chemical that transmits signals between nerve cells called acetylcholine, and (2) increasing the sensitivity of another chemical, called nicotinic acetylcholine receptors (nAChRs), which also enhances acetylcholine, regulates inflammation, defends against the loss of amyloid and strengthens other transmitters within the brain. The Company believes this results in enhancement and improvement of:

- Memory acquisition and retrieval
- Attention and activity
- Stabilization of behavior
- Inhibition of cell death and neuroprotection

The Company's ALPHA-1062 development plan has two primary goals:

- **Clinical Development:** Demonstrate, to the satisfaction of regulatory bodies, that ALPHA-1062 formulations have a significantly reduced side effect profile and differentiated mechanism of action (MOA) from existing acetylcholinesterase inhibitor (AChEI) treatments, with the exception of galantamine's MOA.
- **Regulatory:** Demonstrate that an NDA pathway called a 505(b)(2) is available for approval in the United States, allowing commercialization, that relies on the establishment of a scientific bridge to the findings of safety and efficacy of the FDA approved Razadyne utilizing a bioavailability and bioequivalence pivotal study instead of the traditional efficacy trials.

ALPHA-1062 sublingual formulation will be developed as an alternative formulation for patients who suffer from dysphagia (inability to swallow). A number of Alzheimer's patients are estimated to suffer from dysphagia and utilize alternative liquid or patch formulations for medicine administration. A systematic review (dement Neuropsychol. 2022 Jul-Sep; 16(3): 261-269 estimated dysphagia prevalence of greater than 80% of moderate to severe patients with Alzheimer's. The sublingual formulation would allow for a dissolvable tablet or film strip that could provide medicine to these patients in an alternative method of administration. The formulation is in early development phases and will be advanced after commercialization of ALPHA-1062.

In September 2023 the company filed an NDA for ALPHA-1062 which was accepted for review by Food and Drug Administration (“FDA”) on December 06, 2023. ALPHA-1062 has a Prescription Drug User Fee Act (“PDUFA”) date (drug approval date) in the U.S. for July 27, 2024. If approved, ALPHA-1062 would be the second oral therapy available for Alzheimer's patients in the past decade.

On August 10, 2023, the Company announced the United States Patent and Trademark Office (“USPTO”) issued a Notice of Allowance for patent application No. 17/575,025, titled “Solid Forms of ALPHA-1062 Gluconate,” which includes claims covering protection for crystalline solid forms of ALPHA-1062 and will bolster existing patents that held by the Company. A Notice of Allowance is issued after the USPTO makes the determination that a patent should be granted from an application. This Notice of Allowance signifies a pivotal step forward for the Company and is the result of years of research and development, conducted by Alpha Cognition's team of scientists, researchers, and medical experts.

On July 19, 2023, the Company received FDA confirmation that the Company meets the statutory requirements of the Federal Food, Drug, and Cosmetic Act and granted the Company's request for a small business waiver of the application fee for NDA 218549 for Galantamine Benzoate, provided the marketing application is received by FDA within one year from the date of the letter. The small business waiver of NDA and biologics license application fees could save the Company an amount to up to US\$3,200,000.

#### *ALPHA-1062 Clinical Development*

The original nasal formulation of ALPHA-1062 was used to conduct Phase I human studies, initially by Neurodyn, a former related party through common shareholders, and subsequently, on completion of the ALPHA-1062 license agreement, by the Company. The Phase I human studies included a single ascending dose study (“**SAD Study**”) followed by a multiple ascending dose (“**MAD Study**”) study. These Phase I studies

were designed to determine the safety of the drug, which was administered to healthy subjects, including elderly, at increasing doses of ALPHA-1062, initially one time in the SAD Study, and subsequently multiple times over a seven-day period in the MAD Study. These studies indicated that ALPHA-1062 formulations may have reduced gastrointestinal side effects (nausea, diarrhea, vomiting) as compared to one of the existing treatments; Razadyne (galantamine is the generic name).

**Pivotal Trial:** The Company successfully completed two studies in Q2 2022 and a third in Q3 2022. The studies were designed to demonstrate pharmacokinetic equivalence compared to the reference listed drug galantamine hydrobromide immediate release and galantamine hydrobromide extended release, which are the standard of care treatments for patients with mild to moderate Alzheimer’s disease. Topline results confirmed in bioequivalence studies that ALPHA-1062 achieved bioequivalent area-under-the-curve (fed and fasted) and peak exposures (fed) relative to galantamine hydrobromide immediate release and galantamine hydrobromide extended release. There were minimal adverse events (<3%) reported for ALPHA-1062 during these studies. With these positive pivotal study results, the Company filed an NDA for ALPHA-1062 in mild to moderate Alzheimer’s disease during Q3 2023, with possible FDA approval for the U.S. market by Q3 2024.

The following table summarizes the results of the ALPHA-1062 Pivotal Study BABE Study vs. Immediate Release (completed in June 2022) and an additional BABE Study vs. Extended Release (completed in August 2022).

| BABE Study vs. Immediate Release  |                                       |                                      |                             |                                | BABE Study vs. Extended Release  |                                       |                                     |                             |                                |
|-----------------------------------|---------------------------------------|--------------------------------------|-----------------------------|--------------------------------|----------------------------------|---------------------------------------|-------------------------------------|-----------------------------|--------------------------------|
| PK Parameter                      | ALPHA-1062 Delayed Release 5mg (n=36) | Gal HBr Immediate Release 4mg (n=36) | % to Reference Drug 80-125% | Sufficient Data for NDA Filing | PK Parameter                     | ALPHA-1062 Delayed Release 5mg (n=20) | Gal HBr Extended Release 8mg (n=20) | % to Reference Drug 80-125% | Sufficient Data for NDA Filing |
| AUC0-inf (µg x h/mL) Fasted State | 306.8                                 | 321.5                                | 95%                         | ✓                              | AUC0-24 (µg x h/mL) Steady State | 527.5                                 | 492.1                               | 107%                        | ✓                              |
| Cmax (ng/mL) Fasted State         | 30.7                                  | 40.5                                 | 76%                         | ✓                              | Cmax (ng/mL) Steady State        | 41.7                                  | 32.8                                | 127%                        | ✓                              |
| AUC0-inf (µg x h/mL) Fed State    | 286.7                                 | 329.9                                | 87%                         | ✓                              |                                  |                                       |                                     |                             |                                |
| Cmax (ng/mL) Fed State            | 27.6                                  | 30.2                                 | 91%                         | ✓                              |                                  |                                       |                                     |                             |                                |

- Data confirms **ALPHA-1062 AUC is bioequivalent to galantamine hydrobromide IR and ER**
- Cmax for ALPHA-1062 is bracketed between IR and ER (lower than IR, higher than ER) providing necessary data for NDA filing (scientific bridge)
- **Minimal Adverse Events** reported in these trials of healthy volunteers
- **Allows NDA filing** based on 505(b)(2) requirements

90% Confidence Interval (CI) acceptance criteria is 80-125% for the test/reference ratio

COPYRIGHT 2021 ALPHA COGNITION, INC. 1. Alpha Cognition: Sublingual and Enteric Coated Tablet equivalent to 8 mg RAZADYNE Data on file  
 2. DA Guidance: <https://www.fda.gov/files/drugs/published/Bioavailability-and-Bioequivalence-Studies-Submitted-in-NDAs-or-INDs>

**BABE Study vs. Immediate Release**

The primary objective of both the fed and fasted studies was to evaluate the relative bioavailability of a single-dose of ALPHA-1062 (or galantamine benzoate) 5mg delayed release tablet compared to galantamine hydrobromide tablet 4mg immediate release — the reference drug. Thirty-six healthy subjects were enrolled in each trial.

Two drug products are recognized to be bioequivalent if the 90% confidence interval of the ratio of geometric means of the primary pharmacokinetic (PK) responses (after log-transformation) is within the bioequivalence limits of 80% and 125%.

A secondary objective of the studies was to evaluate the safety and tolerability of single-dose administration of ALPHA-1062 5mg tablet. The primary pharmacokinetic outcomes were AUC or area under the curve, and Cmax, the highest concentration of drug in the blood. The area under the curve represents the total exposure to the active drug galantamine over time after a single administration, and the Cmax represents the highest peak exposure to galantamine.

Bioequivalence of ALPHA-1062 to galantamine hydrobromide was established in both the fed and fasted studies with the 90% confidence intervals for area under the curve falling within the 80%-125% bioequivalence

range. The mean area under the curve ratio to reference drug for ALPHA-1062 was 95% (306.8) in the fasted study and 87% (286.7) in the fed study.

The average C<sub>max</sub> ratio to reference drug for ALPHA-1062 was 76% (30.7) in the fasted study and 91% (27.6) in the fed study both C<sub>max</sub> results being higher than the published C<sub>max</sub> data for galantamine hydrobromide 8 mg extended release capsule. Bioequivalence of ALPHA-1062 has been demonstrated based on overall drug exposure in both the fed and fasted states, and the C<sub>max</sub> with ALPHA-1062's delayed release formulation is expectedly lower than that of the immediate release formulation of galantamine, yet higher than the published data with galantamine extended release capsule. Bioequivalence of ALPHA-1062 was established on C<sub>max</sub> compared to galantamine hydrobromide in the fed state. When the C<sub>max</sub> of a proposed drug product falls between the reported C<sub>max</sub> of two formulations of an approved reference product (immediate and extended release), this allows for an effective scientific bridge to both formulations of the reference standard galantamine hydrobromide.

Single-dose administration of ALPHA-1062 was well tolerated with no adverse events reported.

### BABE Study vs. Extended Release

During August 2022, the Company announced positive results from an additional bioequivalence study with ALPHA-1062. The Company elected to conduct this additional study which was designed to demonstrate pharmacokinetic (PK) equivalence between 5 mg ALPHA-1062 delayed release tablets and 8 mg galantamine hydrobromide extended release capsules, when dosed to steady state. Bioequivalence was established based on total drug exposure (AUC) and the C<sub>max</sub> was expectedly higher than that of the extended release reference. These data, coupled with the positive pivotal data released in June, establish bioequivalence to both formulations of galantamine hydrobromide and strengthen the NDA application for ALPHA-1062 in mild-to-moderate Alzheimer's disease, filed in Q3 2023. The Company prepared and filed the NDA with the FDA and the file is pending FDA review and approval.

The study was a two-treatment, two-period, crossover study wherein 40 subjects were randomly assigned 1:1 to either treatment with ALPHA-1062 5mg twice daily, or galantamine hydrobromide 8mg ER capsules once daily, for 7 days. After a one-week washout period, subjects were then crossed over to the other treatment arm and dosed for 7 days.

Topline results confirmed that in healthy adult volunteers treated to steady state, ALPHA-1062 was bioequivalent to galantamine hydrobromide extended release. In the pre-specified primary analysis, ALPHA-1062 achieved area-under-the-curve and peak exposures (C<sub>max</sub>) of approximately 107% and 127%, respectively, compared to those generated by galantamine hydrobromide extended release. As expected, C<sub>max</sub> results for ALPHA-1062 is bracketed between galantamine hydrobromide immediate release and galantamine hydrobromide extended release (lower than immediate release, higher than extended release) providing a robust and enhanced data set for the NDA filing. These data further describe the delayed release profile of ALPHA-1062 and strengthen the NDA data set by characterizing the therapeutic and acceptable exposures compared to both the immediate release and extended release products.

During the second quarter of 2022, the Company met with FDA regarding the ALPHA-1062 program for mild-to-moderate Alzheimer's disease. The Company received feedback regarding the ALPHA-1062 RESOLVE trial, labeling, and manufacturing. As a result of the agency's feedback, the Company filed its NDA for ALPHA-1062 in mild-to-moderate Alzheimer's disease in Q3 2023, allowing the Company to include additional CMC stability data in the NDA filing. The Company's projected approval date for ALPHA-1062 is Q3 2024.

### **Commercialization Strategy**

#### ALPHA-1062 Alzheimer's Disease Commercialization Strategy

During the second half of 2023 the Company started, in parallel with the Company's regulatory activities, taking steps to develop a commercialization team to ensure a successful launch in the U.S. The Company has completed sufficient planning to indicate that ALPHA-1062 could be launched using a best-in-class specialty sales force that will focus on Long Term Care (LTC) physicians in the U.S.. Long term care physicians who treat elderly patients that reside in nursing homes also make pharmacologic decisions in concert with the LTC treatment team. Our research has indicated that the acetylcholinesterase inhibitor (AChEI) prescription market

in the U.S. from the LTC market is large, representing 36% of the over 11 million prescriptions filled in pharmacies each year. The AChEI class includes Aricept, Exelon, Exelon Patch, Razadyne, Adlarity, Namzaric, and generic versions of the AChEIs. Prescription data suggests that there is currently high turnover of patients treated with currently approved AChEI medications, with 30% of patients discontinuing treatment by month 4 and 55% discontinuing treatment within one year. The Company believes that patients who discontinue a first therapy will try a 2<sup>nd</sup> and 3<sup>rd</sup> line therapy. Patient willingness to try multiple therapeutics provides an opportunity for ALPHA-1062 to take market share in the overall AChEI market. The sales force will message potential key points of label differentiation and exploit key issues with existing AChEI medications. Success will be further enabled by securing product coverage with U.S. payors. Market research indicates that payors are likely to cover ALPHA-1062 if the product is competitively priced. Additionally, the Company intends to seek strategic partnerships to expand promotional efforts and physician promotional coverage. As ALPHA-1062 nears FDA regulatory approval, the Company will seek distribution partners for major territories, identified as Europe, LATAM (Mexico, Central and South America), and Asia. Additionally, the Company intends to seek approval for potential additional indications and product line extensions.

### ***Potential ALPH-1062 coverage and reimbursement in the United States***

The Company believes ALPHA-1062 will have limited payor barriers based on current US access and reimbursement data of generic Alzheimer's Disease symptomatic medications (e.g., acetylcholinesterase inhibitors, memantine) and branded Namzaric<sup>®</sup> which are widely accessible to most MA-covered lives. Donepezil and Namzaric<sup>®</sup> are mostly covered by health care plans.

Third party market research with pharmacy and medical directors, indicates that coverage of ALPHA-1062 would be similar to Namzaric<sup>®</sup>. They forecast ALPHA-1062 to be managed at a preferred or non-preferred branded tier, without PA or step edits, depending on rebates, as long as it is competitively priced and differentiated from other products via its improved tolerability. Importantly, caregiver market research highlights cost is not an issue. They are willing to pay a premium for a product that is more efficacious with less side effects. This provides additional confidence to the Company that family members will request branded ALPHA-1062 for their mild-to-moderate Alzheimer's Disease patients, even at a higher cost than current generics.

### ***Competitive Conditions and ALPHA-1062 Positioning***

Alzheimer's disease symptomatic treatments are currently limited and perceived to provide limited symptom improvement and cause difficult to manage tolerability side effects. Symptomatic treatments are designed to improve the ability to learn, remember key events and loved ones, and function normally with daily tasks like toileting, cooking, or home care. Each year greater than 2 million patients are on medication for the disease, which makes up half of the estimated number of people with Alzheimer's disease in the US. Approximately 70% of patients with mild Alzheimer's disease, 80% with moderate, and 75% with severe Alzheimer's disease are on drug-treatment. On average, it can take up to 2.5 months from diagnosis to treatment, but can take up to 2 years, and roughly 32% will never go on treatment. Patients are treated primarily with symptomatic medications to help the cognitive and functional symptoms of Alzheimer's disease. In addition to symptomatic treatments, patients will also be prescribed behavioral and psychiatric medications for depression, hallucinations, aggression and agitation.

There are four symptomatic drug treatments that have been approved by the FDA to date for mild to moderate Alzheimer's disease.

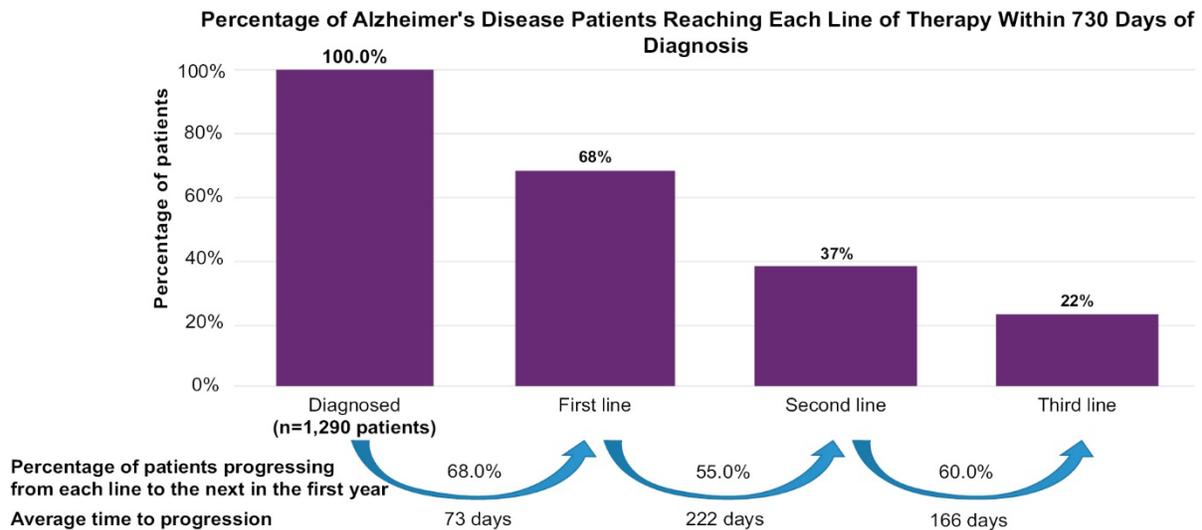
- (1) Donepezil (marketed under the brand name, Aricept by Eisai and Pfizer)
  - a. First-to-market, approved in 1996; generic
  - b. Acetylcholinesterase inhibitor drug class, oral QD medication
  - c. Indicated for mild-to-moderate and moderate-to-severe stages of Alzheimer's disease
- (2) Rivastigmine capsules and patch (marketed under the brand name Exelon/Exelon Patch by Novartis)
  - a. Approved in 2000; 2007 generic
  - b. Exelon capsules: Acetylcholinesterase inhibitor drug class, oral BID tablet and oral solution
  - c. Exelon Patch: Acetylcholinesterase inhibitor drug class, daily transdermal system
  - d. Indicated for mild-to-moderate and moderate-to-severe stages of Alzheimer's disease
- (3) Galantamine (marketed under the brand names Reminyl and Razadyne/Razadyn ER by Janssen)
  - a. Approved in 2001, 2004; generic

- b. Acetylcholinesterase inhibitor drug class, oral BID medication
- c. Indicated for mild-to-moderate stage of Alzheimer’s disease
- (4) Donepezil transdermal system (marketed under the brand name Adlarity by Corium)
  - a. Approved in 2022, branded transdermal patch
  - b. Acetylcholinesterase inhibitor drug class, once-weekly transdermal system
  - c. Indicated for mild-to-moderate and moderate-to-severe stages of Alzheimer’s disease

The FDA recently approved Aducanumab (marketed under the branded name Adulhelm by Biogen) and lecanemab (marketed under the branded name Leqembi by Eisai) for mild-to-moderate Alzheimer’s disease. Adulhelm was the first disease modifying treatment (DMT), but due to several issues associated with the drug, including CMS restricting coverage, it is not easily accessible and will only be covered for qualified clinical trial patients. Leqembi is indicated for the treatment of Alzheimer’s disease. It is expected that coverage and utilization may be better for Leqembi than Adulhelm, but this will only be apparent after several quarters of commercialization. It is important to note that DMT agents will not be a competitor to the current standard of care, the AChEI class. DMTs will be used in combination with these medications, as they do not address the symptoms of the disease.

Alzheimer’s disease is a highly genericized market with limited drug development innovation. As noted above, three out of the four approved symptomatic medications are generic and many have been in the market up to two decades. The acetylcholinesterase inhibitors drug class (i.e.: donepezil 70% market share, rivastigmine 4.86% market share, and galantamine 2.27% market share) are largely prescribed, with approximately 80% of the total Rx market share. N-methyl-D (NMDA) receptor agonists (memantine and branded Namzaric) are indicated for moderate-to-severe Alzheimer’s disease and as such are used in later stages, and as combination therapy with acetylcholinesterase inhibitors. Due to the perceived limited efficacy and side effects of the acetylcholinesterase inhibitor medications, patients are often taking multiple therapies, ultimately increasing their drug burden. ~60% of patients are on combination therapy in hopes of increasing efficacy outcomes and mitigating side effects. Of note, 55% of patients progress to second line therapy, and 60% will progress further to a third line therapy. This further illustrates the unmet needs of current treatment options, but also the patient’s willingness to keep trying medication until something works.

### Treatment Initiation and Progression



Source: Decision Resources Group, 2021

The perceived limited efficacy or not enough efficacy improvement, and tolerability side effects, including gastrointestinal issues (nausea, diarrhea, and vomiting), dizziness and insomnia, cause a substantial rate of treatment discontinuation. Some data and studies suggest that patients on acetylcholinesterase inhibitor medications, will discontinue treatment approximately 30% of the time within 4 months and 55% discontinue therapy within 12 months. Gastrointestinal issues are cited as a leading reason for discontinuing treatment, as reported in both physicians and caregiver market research. The high rates of gastrointestinal adverse effects

are also included in the prescribing information for each approved drug. The most common adverse events that are reported to lead to discontinuation of therapy were diarrhea, nausea, vomiting, dizziness and decreased appetite among acetylcholinesterase inhibitors. Prescribing habits within long-term care physicians, seem to be well entrenched, and overall, physicians report feeling dissatisfied and/or apathetic about their symptomatic treatment options. Caregivers also expresses dissatisfaction with the currently approved symptomatic treatments options.

There is a significant unmet need for better treatment options for patients suffering from Alzheimer’s disease. The company believes that ALPHA-1062 is poised to be a next-generation, best in class treatment option. The company will differentiate ALPHA-1062 based on several potential advantages to Alzheimer’s Disease patients:

- Efficacious cognitive and functional improvement results
- Dual mechanism of action, enhancing the acetylcholine levels and nicotinic receptor sensitivity
- Enteric-coated tablet that bypass the GI as an inactive compound to minimize GI side effects
- Minimal GI side effects (nausea, vomiting, and diarrhea)
- No incidence of insomnia and dizziness

Market research confirms that based on the product attributes listed below, 88% of LTC prescribers are likely to prescribe ALPHA-1062, with a 29% preference share.

 **ALPHA-1062: Offers Potential Best-In-Class Profile Versus Approved AChEIs**

|                                      |                                                                                                                                         | ALPHA-1062 |  <b>Aricept</b> |  <b>Razadyne<sup>ER</sup></b> |  <b>EXELON<sup>®</sup></b> |
|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| <b>GI Safety Profile</b>             | <b>Reduced GI side-effects</b> (diarrhea, nausea, vomiting)                                                                             | ✓          | ✗                                                                                                  | ✗                                                                                                                 | ✗                                                                                                              |
| <b>CNS Safety Profile</b>            | No incidence of insomnia                                                                                                                | ✓          | ✗                                                                                                  | ✓                                                                                                                 | ✗                                                                                                              |
| <b>Long Term Outcome<sup>1</sup></b> | <b>Significant risk reduction</b> in risk of developing severe dementia                                                                 | ✓          | ✗                                                                                                  | ✓                                                                                                                 | ✗                                                                                                              |
| <b>Cognition Effects</b>             | Demonstrated strongest effect on cognition                                                                                              | ✓          | ✗                                                                                                  | ✓                                                                                                                 | ✗                                                                                                              |
| <b>Mechanism of Action</b>           | <b>Dual mechanisms of action</b> that potentiate acetylcholine transmission and modulate nAChR ( $\alpha7/\alpha4\beta2$ ) <sup>2</sup> | ✓          | ✗                                                                                                  | ✓                                                                                                                 | ✗                                                                                                              |

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ARICEPT is a registered trademark of Eisai Co., Ltd.  
 RAZADYNE is a registered trademark of Johnson & Johnson  
 EXELON is a registered trademark of Novartis Pharmaceuticals Corp

1. Xu et al. Neurology 96 (17) e2221 (2021)  
 2. Feldman et al. International Journal of Geriatric Psychiatry 2009; 24: 479-488

<sup>®</sup>Rivastigmine is also available as a transdermal patch

**Alzheimer’s Disease Moderate-To-Severe Stage Program**

**Disease and Market Overview**

Our second program in early clinical trials is a combination oral product for moderate-to-severe Alzheimer’s Disease. The Company believes combining ALPHA-1062 with previous FDA approved NMDA receptor memantine would provide differentiating efficacy and an attractive tolerability profile to patients within these advance stages. Moderate Alzheimer’s Disease and severe Alzheimer’s Disease affects a total of ~1.4M patients in the United States. In 2020, over 7 million Rx’s were written for the memantine-containing product. In the moderate stage of Alzheimer’s Disease symptoms becomes more intense, significantly affecting their everyday life. They have difficulties with communication and personality and behavioral changes present. The caregiver burden also increases during this stage, as many activities (dressing, bathing, bathroom) require assistance and management. In the severe stage of the disease, patients will experience more robust and debilitating symptoms. The complete deterioration of cognition and functional abilities require round-the-clock care, eating and drinking prove difficult, and they usually become bed bound. On average 40% of the final years

of an Alzheimer's Disease patients (ages 70 to 80 years old) will be spent in the severe stage and the nature of the symptoms leads to the vast majority being admitted into a Long-Term Care facility.

### ***Our Product and Approach to Treatment***

The Company plans to develop ALPHA-1062+ Memantine, a combination of ALPHA-1062 and Namenda XR, to simplify the co-administration of these drugs by a patient or caregiver with the goal of increasing compliance and adherence to the prescribed regimen. We believe that ALPHA-1062 + Memantine has the potential to be adopted by patients already taking Namzaric® or generic combination therapy as well as moderate to severely affected patients currently taking donepezil or memantine alone.

Once the Company receives approval for ALPHA-1062 for the treatment of mild-to-moderate dementia associated with Alzheimer's Disease, it plans to initiate a streamlined 505(b)2 regulatory path for approval of ALPHA-1062 + memantine. With FDA approval, the Company believes ALPHA-1062 + memantine would have the potential to provide differentiating product characteristics including, 3 mechanisms of action and a minimal side effect profile for the treatment of moderate-to-severe dementia associated with Alzheimer's Disease. The Company believes ALPHA-1062 & memantine will be absorbed through the gastrointestinal tract; ALPHA-1062 inertly with minimal gastrointestinal side effects and memantine with acceptable side effects when up-titrated. The combination therapy will act via 3 distinct mechanisms of action acetylcholinesterase inhibition, enhanced nicotinic receptor activity and sensitivity, and NMDA receptor antagonism. The Company believes ALPHA-1062 + memantine could capture substantial market share due to physicians' established practice of prescribing combination therapies in later stages of Alzheimer's Disease and patients' acceptance of multiple medications.

With the approval of both ALPHA-1062 and the combination therapy (ALPHA-1062+Memantine), the Company would be able to offer a solution that treats all the stages of Alzheimer's Disease.

### **TBI Out-Licensing Plan**

**TBI Out-License** The Company obtained shareholder approval to out-license ALPHA-1062IN for applications in treating mild traumatic brain injury ("mTBI") and TBI to Alpha Seven Therapeutics Inc. ("Alpha Seven") a newly incorporated entity. Alpha Seven will focus its business on the advancement of the use of ALPHA-1062IN for the treatment of TBI and mTBI with a focus on using intra-nasal delivery, including advancing clinical trials and FDA approval. The establishment of Alpha Seven provides for the separate funding and advancement of the TBI and mTBI applications of ALPHA-1062 while permitting the Company to remain focused on advancing ALPHA-1062 for use in the treatment of symptoms of Alzheimer's disease.

The Company met with the U.S. Food and Drug Administration (the "FDA") in a pre-investigational new drugs ("IND") meeting in Q2, 2023. The meeting was scheduled to align with FDA on pre-clinical, clinical, and manufacturing items necessary to file an IND and initiate a Phase 2 trial for ALPHA-1062IN. As a result of FDA feedback, and following the out-licensing to Alpha Seven and its needed capital raise, Alpha Seven will be in a position to complete additional manufacturing and toxicity work which will allow Alpha Seven to initiate a Phase 2 clinical study.

An agent has agreed, to conduct a financing for Alpha Seven in exchange for an initial 37.5% ownership interest in Alpha Seven, with the Company initially retaining 47.5% ownership and key management of Alpha Seven ("Alpha Seven Management") is expected to initially hold the remaining 14.6% ownership interest, managements ownership is subject to a one-year vesting period. The agent's interest will be subject to completion of an initial financing for gross proceeds to Alpha Seven of \$2.2 million.

Alpha Seven's current management is as follows: Michael McFadden, the Chief Executive Officer and a director of the Company, serves as the Chief Executive Officer of Alpha Seven, and Lauren D'Angelo, the Chief Operating Officer of the Company, serves as the Chief Operating Officer of Alpha Seven.

The establishment and funding of Alpha Seven as described above is at the proposal stage only. There is no guarantee that the Company will be successful launching Alpha Seven as a separately funded entity as described above or at all. There is no guarantee that Alpha Seven will be successful in advancing the ALPHA-1062 for use in TBI or mTBI.

***ALPHA-1062 Manufacturing***

With respect to the manufacturing of ALPHA-1062, the Company has entered into agreements with specialized contract manufacturing organizations located in Taiwan for the manufacturing of the ALPHA-1062 active pharmaceutical ingredient, and with manufacturing companies located in the United States specialized in the production of oral tablets and nasal spray formulations. As the development program proceeds, the Company intends to contract with back-up active pharmaceutical ingredient and contract manufacturing organizations, ensuring a reduced risk of disruption in the supply of the product on commercialization. The Company expects that this strategy will help reduce the operational risk.

ALPHA-0602, ALPHA-702 and ALPHA-802 are in pre-clinical studies and not yet in the production phase.

***ALPHA-1062 Clinical Testing***

The Company contracted with Contract Research Organizations (CROs) to conduct both pilot and pivotal BABE clinical trials. Based on historical experience with inspections of these CROs, as well as audits and monitoring conducted by the Company at these sites, the Company is satisfied that the CROs and sites meet the international and FDA standards required for successful conduct of the Pilot Pivotal Studies required for NDA approval.

***ALPHA-1062 Regulatory Matters***

The Company has entered into contracts with regulatory consultants to provide advice and assist in preparing documentation for regulatory submissions to the FDA. The Company also plans to contract with appropriate regulatory consultants focused on the European Medicines Agency (EMA) of the European Union.

The Company intends to develop a detailed commercialization plan which is subject to the receipt of FDA approval for ALPHA-1062, in the United States. The Company also intends to identify pharmaceutical distribution partners to enter the markets in Asia, European Union, and/or LATAM (Mexico, Central and South America).

The Company is in discussions with several pharmaceutical distributors with respect to LATAM (Mexico, Central and South America) and select Asian countries. Following an FDA registration, the Company anticipates that it may be possible to enter into license agreements in several of these non-core territories. As at the date of this Memorandum, no formal licensing or marketing agreements have been entered into, however, initial discussions have been held with distributors in several non-core territories.

**Government Regulation**

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, nonclinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing. Generally, before a new drug can be marketed, considerable data must be generated, which demonstrate the drug's quality, safety, and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Pre-Clinical Assets - ALPHA-0602, ALPHA-0702 and ALPHA-0802

***Amyotrophic Lateral Sclerosis (ALS) or Lou Gehrig's disease: ALPHA-0602 (Progranulin and Granulin Epithelin Modules)***

The Company has preclinical assets which include ALPHA-0602 (Progranulin) is expressed in several cell types in the central nervous system and in peripheral tissues, promotes cell survival, regulates certain inflammatory processes, and plays a significant role in regulating lysosomal function and microglial responses to disease. Its intended use for the treatment of neurodegenerative diseases has been patented by the Company and ALPHA-0602 has been granted an Orphan Drug Designation for the treatment of ALS by the FDA. ALPHA-0702 and ALPHA-0802 are Granulin Epithelin Motifs, ("GEMs"), derived from full length progranulin which have therapeutic potential across multiple neurodegenerative diseases. GEMs have been

shown to be important in regulating cell growth, survival, repair, and inflammation. ALPHA-0702 and ALPHA-0802 are designed to deliver this with potentially lower toxicity, and greater therapeutic effect.

The Company's product candidate, ALPHA-0602, previously referred to as 'full length Progranulin', is a protein that regulates cell growth, cell survival, cell repair, and inflammation in both central nervous system and peripheral tissues. Low progranulin levels are a risk factor for Amyotrophic Lateral Sclerosis Parkinson's Disease, Frontotemporal Disorders (FTD) and other central nervous system disorders. Increasing progranulin in the brain is a promising avenue for a novel Amyotrophic Lateral Sclerosis treatment. ALPHA-0602 has demonstrated positive proof of concept results in an *in vitro* data in neurons and *in vivo* orthotype model of Amyotrophic Lateral Sclerosis, indicating that progranulin may be effective in modifying the disease process. The company has paused further development of ALPHA-0602 and the granulin program and will seek to out-license the assets.

### **Current Year Summary**

On January 16, 2023, the Company repriced 4,655,000 stock options with exercise prices ranging from CAD\$0.64 to CAD\$1.05. The new options have an exercise price of CAD\$0.28 per share and vest in monthly installments over either an 8 month, 18 month or 24 month term.

On March 6, 2023, the Company closed the Q1 2023 PP as described above under the heading "Capital Raised Q1 2023".

On March 6, 2023, the Company and NLS agreed to an amendment to the promissory note pursuant to which the interest rate was increased from 2% to 5.5% and the maturity date was extended from December 31, 2022 to July 15, 2024. The amended agreement was effective March 1, 2023, and required monthly interest only payments until maturity. In addition, the amendment now incorporates both Alpha Cognition, Inc. and Alpha Cognition Canada, Inc. under the Memogain Technology License Agreement and added clarity to certain terms and definitions under the license agreement.

As of May 1, 2023, the Company's common shares commenced trading on the Canadian Securities Exchange ("CSE") under the symbol "ACOG", previously the Company's shares were traded on the TSX Venture Exchange ("TSX-V") until April 28, 2023, when the Company had them delisted. The symbols "ACOG" and "ACOG.WT" remained unchanged.

On May 1, 2023, the Company issued 1,050,000 Common Shares in relation to the exercise of 1,050,000 ACI Canada legacy performance options with an exercise price of \$0.01 for total proceeds of \$10,500.

On June 8, 2023, the Company granted 16,190,000 Common Share options with an exercise price of CAD\$0.22 per share to certain employees of ACI USA and certain directors of the Company. The options will be subject to the following vesting terms: 12.5% will vest on June 8, 2023, and the remaining 87.5% will vest in equal monthly instalments until January 30, 2026.

On May 30, 2023, the Company agreed to enter into an ongoing consulting services agreement for a three-year term with Spartan. The services include advising and assisting on potential business development transactions, strategic introductions, assisting management with enhancing corporate and shareholder value, and capital raising advice. Under the terms of the consulting services agreement, the Company will pay Spartan a consulting fee in the aggregate amount of \$480,000, payable in three equal installments with each installment being subject to the Company achieving certain business development and capital raising objectives. Spartan will also be entitled to earn and receive additional common shares of the Company such that Spartan will hold 10.6% of the outstanding common shares of the Company determined as at the closing of the offering, inclusive of the 2,129,566 common shares currently held by Spartan. The additional common shares will be issued to Spartan on a rolling basis upon completion of predetermined business development objectives including the closing of certain offering amounts and the completion of material business transactions. On November 8, 2023, the Company paid \$160,000 in consulting fees pursuant to the Spartan Consulting Agreement. See subsequent events section below for further details on payments.

On June 5, 2023, the Company was awarded a \$750,000 research and development grant from the Army Medical Research and Materiel Command for a pre-clinical study on the use of the ALPHA-1062 Intranasal to reduce blast mTBI (mild Traumatic Brain Injury) induced functional deficit and brain abnormalities ("R&D Grant"). The study grant is issued in collaboration with the Seattle Institute of Biomedical and Clinical Research and is endorsed by the Department of Defense. The study work was initiated in Q3 2023 and expected to continue for a 16 month period. As of December 31, 2023, the Company has received \$201,500 from the grant, which has been recorded as restricted cash on the balance sheet and recorded \$191,087 in related R&D expenses and other income.

On July 7, 2023, the Company entered into a loan agreement with Alpha Seven Therapeutics, Inc. ("Alpha Seven"), a newly formed corporation in which the Company will initially own 47.5% of the common stock and another 14.6% by certain management of the Company, to advance an amount up to \$150,000. The outstanding balance will have an interest rate of 12% per annum and a term of 12 months to July 7, 2024. As of December 31, 2023, the Company has advanced \$55,000 to Alpha Seven.

On August 29, 2023, all 7,000,000 previously outstanding Restricted Shares were converted to Common Shares for nil proceeds.

On August 31, 2023, the Company completed the initial closing of the ongoing Q2 2023 PP where the Company issued 6,114,058 units at a price of \$0.22 for total proceeds of \$1,345,093 ("Q2 2023 PP Tranche 1"). Each unit consists of one Common Share and one-half warrant exercisable at \$0.31 per warrant with an expiry August 31, 2026. In connection with the Q2 2023 PP Tranche 1, the Company paid cash commissions of \$180,051 and issued 272,803 agents warrants with an estimated fair value of \$44,292. Each agent warrant is exercisable into one Common Share of the Company at an exercise price of \$0.31 until August 31, 2026.

On October 1, 2023, 9,602,500 warrants with an exercise price of CAD\$1.75 and 659,627 warrants with an exercise price of CAD\$1.50 expired unexercised.

On October 10, 2023, the Company issued 1,650,000 Common shares in relation to the exercise of 1,650,000 ACI Canada legacy performance options with an exercise price of \$0.01 for total proceeds of \$16,500.

On October 16, 2023, the Company completed the second closing of the Q2 2023 PP by issuing 1,596,830 units at a price of \$0.22 for total gross proceeds of \$351,303 ("Q2 2023 PP Tranche 2"). Each unit consists of one Common Share and one-half of a warrant with each whole warrant entitling the holder to purchase an additional Common Share of the Company at the initial pricing of \$0.31 per share until October 16, 2026. In connection with the closing of Q2 2023 PP Tranche 2, the Company paid cash commissions of \$51,600 and issued 78,181 agents warrants with an estimate fair value of \$10,199. Each agent warrant is exercisable into one Common Share of the Company at an exercise price of \$0.31 until October 16, 2026.

On November 8, 2023, the Company completed the third closing of the Q2 2023 PP by issuing 4,590,903 units at a price of \$0.22 for total gross proceeds of \$1,009,999 ("Q2 2023 PP Tranche 3"). Each unit consists of one Common Share and one-half of a warrant with each whole warrant entitling the holder to purchase an additional Common Share of the Company at the initial pricing of \$0.31 per share until November 8, 2026. In connection with the closing of Q2 2023 PP Tranche 3, the Company paid cash commissions of \$151,500 and issued 229,544 agents warrants with an estimated fair value of \$24,692. Each agent warrant is exercisable into one Common Share of the Company at an exercise price of \$0.31 until November 8, 2026. The Company also paid a consulting fee of US\$160,000 pursuant to the Spartan Consulting Agreement.

On December 4, 2023, the Company amended the terms of the Q2 2023 PP. Each unit will now consist of one common share and one warrant. Each warrant will entitle the holder to purchase an additional common share of the Company at \$0.31 per share for a period of three years from the closing date.

On December 22, 2023, the Company completed the fourth closing of the Q2 2023 PP by issuing 9,141,534 units at a price of \$0.22 for total gross proceeds of \$2,011,137 ("Q2 2023 PP Tranche 4"). Each unit consists of one Common Share and one warrant with each warrant entitling the holder to purchase an additional Common Share of the Company at the initial pricing of \$0.31 per share until December 22, 2026. In connection with the closing of Q2 2023 PP Tranche 4, the Company paid cash commissions of \$238,515 and issued

722,771 agents warrants with an estimated fair value of \$249,965. Each agent warrant is exercisable into one Common Share of the Company at an exercise price of \$0.31 until December 22, 2026.

On December 19, 2023, 251,101 Common Share options with an exercise price of CAD\$0.22 per share were exercised on a cash-less basis resulting in the issuance of 165,000 Common Shares.

On December 31, 2023, 11,317,750 warrants originally issued on February 16, 2023, had their exercise price modified from CAD\$0.39 to \$0.283 and 459,586 warrants originally issued on March 15, 2023 had their exercise price modified from CAD\$0.39 to \$0.289, no change was made to any expiry dates.

### **Subsequent Events**

On January 19, 2024, the Company completed the fifth and final closing of the Q2 2023 PP by issuing 16,965,762 units at a price of \$0.22 for total gross proceeds of \$3,732,468 ("Q2 2023 PP Tranche 5"). Each unit consists of one Common Share and one warrant with each warrant entitling the holder to purchase an additional Common Share of the Company at the initial pricing of \$0.31 per share until January 19, 2027. In connection with the closing of Q2 2023 PP Tranche 2, the Company paid cash commissions of \$342,320 and issued 1,037,330 agents warrants. Each agent warrant is exercisable into one Common Share of the Company at an exercise price of \$0.31 until January 19, 2027. The Company also paid to certain finder's aggregate cash commission of \$48,858, being 6% of the gross proceeds raised under the offering from investors introduced to the Company by such finders.

In January 2024, the Company paid Spartan the remaining consulting fee of \$320,000 and issued 14,558,285 common shares to Spartan and its assignees pursuant to the Spartan Consulting Agreement.

In January 2024, 272,840 Common Share options with an exercise price of CAD\$0.22 per share were exercised on a cashless basis resulting in the issuance of 192,500 Common Shares.

Effective April 1, 2024, the Company and NLS agreed to another amendment to the promissory note pursuant to which the interest rate was increased from 5.5% to 7% and the maturity date was extended from July 2024 to July 2025. Additionally, \$300,000 is now due on December 31, 2024 with the remaining principal balance due at maturity.

Subsequent to the year ended December 31, 2023, 3,322,471 warrants originally issued on February 16, 2023, had their exercise price modified from CAD\$0.39 to \$0.283 and 6,097,579 warrants originally issued on March 15, 2023, had their exercise price modified from CAD\$0.39 to \$0.289. No change was made to any expiry dates.

### **CRITICAL JUDGEMENTS AND ESTIMATES**

The preparation of the condensed interim consolidated financial statements in conformity with IFRS requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported revenues and expenses during the period. Although management uses historical experience and its best knowledge of the amount, events or actions to form the basis for judgments and estimates, actual results may differ from these estimates. Significant estimates and judgements made by management in the preparation of these consolidated financial statements are outlined below.

#### **Functional currency**

Management is required to assess the functional currency of each entity of the Company. In concluding on the functional currencies of the parent and its subsidiaries, management considered the currency that mainly influences the sale prices of goods and services and the cost of providing goods and services in each jurisdiction in which the Company operates. When no single currency was clearly dominant, the Company also considered secondary indicators including the currency in which funds from financing activities are denominated and the currency in which funds are retained.

Income taxes

In assessing the probability of realizing income tax assets, management makes estimates related to expectation of future taxable income, applicable tax opportunities, expected timing of reversals of existing temporary differences and the likelihood that tax positions taken will be sustained upon examination by applicable tax authorities. In making its assessments, management gives additional weight to positive and negative evidence that can be objectively verified.

Going concern

The assessment of the Company's ability to continue as a going concern involves management judgement about the Company's resources and future prospects.

Impairment of intangible assets

The application of the Company's accounting policy for intangible assets requires judgment in determining whether it is likely that future economic benefits will flow to the Company and whether any impairment indicators exist, which may be based on assumptions about future events or circumstances. Estimates and assumptions may change if new information becomes available. If, after expenditures are capitalized, information becomes available suggesting that the recovery of expenditures is unlikely, the amount capitalized is written off in profit or loss in the period the new information becomes available.

Useful lives of intangible assets

Amortization is recorded on a straight-line basis based upon management's estimate of the useful life and residual value. The estimates are reviewed at least annually and are updated if expectations change as a result of technical obsolescence or legal and other limits to use.

Share-based payment transactions and valuation of derivative liability

The Company uses the Black-Scholes Option Pricing Model to determine the fair value of stock options, standalone share purchase warrants issued, bonus rights and derivative liability. This model requires the input of subjective assumptions including expected share price volatility, interest rate, and forfeiture rate. Changes in the input assumptions can materially affect the fair value estimate and the Company's earnings (loss) and equity reserves.

Valuation of bonus rights

The Company uses the Black-Scholes Option Pricing Model to determine the fair value of the bonus rights. This model requires the input of subjective assumptions including expected share price volatility, interest rate, and forfeiture rate. Additionally, the Company applies a probability of the likelihood of certain thresholds being met. Changes in the input assumptions can materially affect the fair value estimate and the Company's earnings (loss) and equity reserves.

**SELECTED ANNUAL INFORMATION**

The following financial data is derived from the Company's audited consolidated financial statements for the years ended December 31, 2023, 2022 and 2021.

|                                         | Year ended December 31, |              |              |
|-----------------------------------------|-------------------------|--------------|--------------|
|                                         | 2023                    | 2022         | 2021         |
|                                         | \$                      | \$           | \$           |
| Operating expenses                      | (9,946,029)             | (13,638,504) | (12,096,888) |
| Other income (expenses)                 | (3,826,538)             | 1,523,806    | (7,448,128)  |
| Net loss                                | (13,772,567)            | (12,114,698) | (19,545,016) |
| Currency translation adjustment         | (19,573)                | 16,806       | (101,534)    |
| Comprehensive loss                      | (13,792,140)            | (12,097,892) | (19,646,550) |
| Basic and diluted loss per common share | (0.15)                  | (0.17)       | (0.37)       |
| Working capital (deficiency)            | (706,463)               | (1,724,103)  | 10,367,955   |
| Adjusted working capital (deficiency)   | (716,876)               | (1,724,103)  | 10,367,955   |
| Total assets                            | 2,452,170               | 2,950,951    | 12,880,368   |
| Total long-term liabilities             | 4,539,872               | 205,989      | 2,048,127    |

*\*Adjusted working capital equals current assets less current liabilities less restricted cash and accrued expenses relating to the R&D Grant.*

Effective August 31, 2023, ACI's functional currency was changed from the Canadian dollar ("CAD") to the US dollar ("USD"). The functional currency of the subsidiaries remained the USD.

**RESULTS OF OPERATIONS – Year Ended December 31, 2023**

During the year ended December 31, 2023, the Company's primary focus was on the continued development and NDA file preparations of ALPHA-1062 in AD.

For the year ended December 31, 2023, operating expenses decreased by \$3,692,475 from \$13,638,504 in the year ended December 31, 2022 to \$9,946,029 in the year ended December 31, 2023 primarily as a result of:

| <b>Operating Expense</b>     | <b>Increase / Decrease in Expenses</b> | <b>Explanation for Change</b>                                                                                                                                                                                                                    |
|------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Financing costs              | Decrease of \$105,168                  | Decreased due to a decrease in the accretion of the NLS promissory note after the amendment of the terms in March 2023                                                                                                                           |
| Investor relations           | Decrease of \$159,967                  | Decreased due to reduction in services provided by investor relations firms in the current year.                                                                                                                                                 |
| Management fees and salaries | Increase of \$107,781                  | Increased primarily due to accrual of 2023 earned yearend bonuses higher than the 2022 yearend bonuses accrual.                                                                                                                                  |
| Professional fees            | Decrease of \$155,318                  | Decreased primarily due to Company cost cutting efforts and its main focus on the development and NDA filing for ALPHA-1062 in AD.                                                                                                               |
| Research and development     | Decrease of \$3,818,589                | Decreased primarily related to lower clinical trial costs related to ALPHA-1062 in AD, as related clinical activities were substantially completed during 2022. 2023 expenses were more heavily focused on R&D for the NDA filing related costs. |
| Share-based compensation     | Increase of \$678,463                  | Increased due to stock options granted in January 2023 and June 2023 at current market pricing that are subject to graded vesting.                                                                                                               |
| Subcontractors               | Decrease of \$225,280                  | Decreased due to a reduction of the use of subcontractors from the prior year.                                                                                                                                                                   |

The following occurred during the year ended December 31, 2023 as compared to the year ended December 31, 2022:

- the Company recorded an increase of \$305,985 in foreign exchange gain due to the changes in the foreign exchange rate between the USD and CAD;
- the Company recognized \$260,503 of income from the R&D grant and Federal Employee Retention Credits during the year; and
- the Company recorded a decrease in the gain on the derivative liability of \$5,908,728 resulting from a decrease of \$1,969,424 on the revaluation of the derivative liability relating to the warrants with an exercise price in USD prior to the Company's August 31, 2023 change in functional currency, and a decrease of \$3,939,304 on the revaluation of the derivative liability relating to the warrants with an exercise price in CAD following the Company's August 31, 2023 change in functional currency.

**SUMMARY OF QUARTERLY RESULTS FOR THE LAST CONSECUTIVE EIGHT QUARTERS**

The following table presents the unaudited summarized financial information for the last eight quarters:

|                                   | <b>Q4<br/>2023</b> | <b>Q3<br/>2023</b> | <b>Q2<br/>2023</b> | <b>Q1<br/>2023</b> |
|-----------------------------------|--------------------|--------------------|--------------------|--------------------|
|                                   | \$                 | \$                 | \$                 | \$                 |
| Operating expenses                | (2,359,827)        | (2,829,663)        | (2,752,599)        | (2,003,940)        |
| Other income (expenses)           | (3,437,248)        | (493,603)          | (38,155)           | 142,468            |
| Loss for the period               | (5,797,075)        | (3,323,266)        | (2,790,754)        | (1,861,472)        |
| Currency translation adjustment   | -                  | (11,232)           | 27,898             | (36,239)           |
| Comprehensive loss for the period | (5,797,075)        | (3,334,498)        | (2,762,856)        | (1,897,711)        |
| Loss per share                    | (0.05)             | (0.03)             | (0.03)             | (0.02)             |
| Weighted average shares           | 107,601,407        | 97,010,836         | 94,604,510         | 77,849,023         |

|                                            | <b>Q4<br/>2022</b> | <b>Q3<br/>2022</b> | <b>Q2<br/>2022</b> | <b>Q1<br/>2022</b> |
|--------------------------------------------|--------------------|--------------------|--------------------|--------------------|
|                                            | \$                 | \$                 | \$                 | \$                 |
| Operating expenses                         | (3,420,717)        | (2,857,472)        | (4,417,993)        | (2,942,322)        |
| Other income (expenses)                    | (696,114)          | 782,268            | 1,414,160          | 28,998             |
| Income (loss) for the period               | (4,116,831)        | (2,075,204)        | (3,003,833)        | (2,913,324)        |
| Currency translation adjustment            | 873,874            | (680,619)          | (376,526)          | 200,007            |
| Comprehensive income (loss) for the period | (3,242,957)        | (2,755,823)        | (3,380,359)        | (2,713,247)        |
| Loss per share                             | (0.05)             | (0.04)             | (0.05)             | (0.04)             |
| Weighted average shares                    | 68,023,450         | 68,023,450         | 68,023,450         | 67,815,580         |

The variations in net loss from quarter to quarter are primarily a result of the extent of the amount of administrative expenses incurred, the amount of activity the Company is incurring on the research and development of ALPHA-1062 and ALPHA-0602, and the amount of net change in the derivative liability.

The following one-time events also occurred:

- Q4 2023 included a loss of revaluation of the derivative liabilities of \$3,552,855 relating to warrants with an exercise price of CAD.
- Q3 2023 included a loss on revaluation of the derivative liabilities of \$515,771 which consisted of the revaluation of the derivative liability relating to the warrants with an exercise price in USD and the revaluation of the derivative liability relating to warrants with an exercise price in CAD currency following the Company's Q3 2023 change in functional currency;
- Q2 2022 included a gain on the revaluation of the derivative liability of \$1,266,779; and
- Q4 2021 included a loss on the revaluation of derivative liability of \$1,106,143.

## RESULTS OF OPERATIONS – Three Months Ended December 31, 2023

During the three months ended December 31, 2023, the Company's primary focus was on the continued development and NDA file preparations of ALPHA-1062 in AD.

For the three months ended December 31, 2023, operating expenses decreased by \$1,060,890 from \$3,420,717 in the three months ended December 31, 2022, to \$2,359,827 in the three months ended December 31, 2023 primarily as a result of:

| Operating Expense            | Increase / Decrease in Expenses | Explanation for Change                                                                                                                                                                                                                           |
|------------------------------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Management fees and salaries | Increase of \$178,292           | Increased due to accrual recorded in the period of 2023 yearend bonuses higher than the same period of 2022 for yearend bonuses.                                                                                                                 |
| Professional fees            | Decrease of \$103,470           | Decreased primarily due to Company cost cutting efforts and its main focus on the development and NDA filing for ALPHA-1062 in AD.                                                                                                               |
| Research and development     | Decrease of \$1,297,055         | Decreased primarily related to lower clinical trial costs related to ALPHA-1062 in AD, as related clinical activities were substantially completed during 2022. 2023 expenses were more heavily focused on R&D for the NDA filing related costs. |
| Share-based compensation     | Increase of \$185,934           | Increased due to stock options granted in January 2023 and June 2023 at current market pricing that are subject to graded vesting.                                                                                                               |

The following also occurred during the three months ended December 31, 2023, as compared to the three months ended December 31, 2022:

- the Company recorded an increase of \$874,769 in foreign exchange loss due to the changes in the foreign exchange rate between the USD and CAD;
- the Company recognized \$227,746 of income from the R&D grant and Federal Employee Retention Credits during the year; and
- the Company recorded a decrease of \$3,717,813 in the gain on derivative liability on the revaluation of the derivative liability relating to the warrants with an exercise price in CAD.

## LIQUIDITY AND CAPITAL RESOURCES

The Company has not generated revenues from its operations to date and as at December 31, 2023, had a deficit of \$63,353,768 (December 31, 2022 - \$49,986,851) which has been primarily financed by equity. The Company had \$1,404,160 in cash, \$90,413 in restricted cash and \$2,624,902 in current liabilities as of December 31, 2023. The Company's continuing operations, as intended, are highly dependent upon its ability to obtain additional funding and generate cash flows. Management is of the opinion that it does not have sufficient working capital to meet the Company's liabilities and commitments as outlined and planned. Management recognizes it will need to raise additional financing to cover upcoming planned NDA filing expenses, research and development, commercialization and operating costs. Possible sources of such capital may come from private placements and public offerings of the Company's common shares and funds received from the exercise of warrants and share options, the Company will also consider funding that may arise through partnerships activities and debt. There is a risk that additional financing will not be available on a timely basis, on terms acceptable, or at all to the Company. These factors indicate the existence of a material uncertainty which causes significant doubt in the ability of the Company to continue as a going concern.

Since the third quarter of 2022 the Company has maintained its initiated cost cutting measures to extend its cash runway and reduce ongoing cash burn. The Company streamlined R&D programs and has prioritized spend towards the NDA filing and development of ALPHA-1062 in AD. The Company has reduced headcount and other operating costs related to the ALPHA-1062 NDA file and other development costs. The Company

has lowered its operating burn until additional capital to support planned commercialization and operations can be secured. If we are unable to raise adequate funds, we may have to further delay or reduce the scope, slow the pace of or eliminate some or all of our current research and development and planned commercial preparation activities. Any of these actions could have a material adverse effect on our business, results of operations or financial condition.

On January 19, 2024, the Company completed the fifth and final closing of the Q2 2023 PP by issuing 16,965,762 units at a price of \$0.22 for total gross proceeds of \$3,732,468 ("Q2 2023 PP Tranche 5"). Each unit consists of one Common Share and one warrant with each warrant entitling the holder to purchase an additional Common Share of the Company at the initial pricing of \$0.31 per share until January 19, 2027. In connection with the closing of Q2 2023 PP Tranche 2, the Company paid cash commissions of \$342,320 and issued 1,037,330 agents warrants. Each agent warrant is exercisable into one Common Share of the Company at an exercise price of \$0.31 until January 19, 2027.

In connection with the final closing, Spartan Capital Securities, LLC ("Spartan") received cash compensation of US\$342,320 and was issued 1,037,330 compensation warrants of the Company, which may be exercised on the same terms as the private placement warrants. The Company also paid to certain finder's aggregate cash commission of US\$48,858, being 6% of the gross proceeds raised under the offering from investors introduced to the Company by such finders.

The table below sets forth a summary of cash flow activity and should be read in conjunction with the Company's cash flow statements included in the Interim Financial Statements:

|                                                       | 2023        | Year ended<br>December 31,<br>2022 |
|-------------------------------------------------------|-------------|------------------------------------|
|                                                       | \$          | \$                                 |
| Cash flows used in operating activities               | (8,728,780) | (9,241,650)                        |
| Cash flows (used in) provided by investing activities | -           | (4,876)                            |
| Cash flows provided by financing activities           | 8,159,230   | 24,785                             |
| Effect of foreign exchange on cash                    | (19,573)    | 3,644                              |
| Decrease in cash during the year                      | (589,123)   | (9,218,097)                        |
| Cash, beginning of year                               | 2,083,696   | 11,301,793                         |
| Cash, end of year                                     | 1,494,573   | 2,083,696                          |
| Cash consists of:                                     |             |                                    |
| Cash                                                  | 1,404,160   | 2,083,696                          |
| Restricted cash                                       | 90,413      | -                                  |
|                                                       | 1,494,573   | 2,083,696                          |

The cash flows used in operating activities decreased by \$512,870 for the year ended December 31, 2023 compared to the comparative year. The decrease in cash flows from operating activities represents the effect on cash flows from net losses adjusted for items not affecting cash, principally: accrued interest income, accretion expense, amortization and depreciation, share-based compensation, and changes in the value of derivatives, in addition to net changes in non-cash balances relating to operations.

Cash provided by financing activities for the year ended December 31, 2023, increased by \$8,134,445 for the year ended December 31, 2023 compared to the comparative year. During the year ended December 31, 2023, financing activities primarily consisted of raising proceeds of \$9,223,587 from units issued for cash and \$27,000 from the exercise of Common Stock options and receiving \$201,500 in government grant proceeds offset by \$111,087 of related expenses. The funds raised under financing activities were offset by share issuance costs of \$1,055,985 and the issuance of a related party note of \$55,000.

## OFF BALANCE SHEET ARRANGEMENTS

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The Company did not have any off-balance sheet arrangements as at December 31, 2023 or the date of this report.

## COMMITMENTS

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### 1) ALPHA-1062 Technology

In March 2015, the Company entered into the Memogain Technology License Agreement ("License Agreement") with NLS for the exclusive right and license to further develop and exploit the Alpha 1062, formerly Memogain Technology. The License Agreement set out the consideration as follows:

- The Company assumed all of NLS's obligations under the Memogain Asset Purchase Agreement which consisted of cumulative total payments to Galantos Pharma GmbH of €10,000,000, the cumulative total may be increased to €15,000,000 subject to certain provisions, which is to be paid as follows (collectively the "Galantos Royalty Payments"):
  - 3% of the net sales revenue received by the Company from the sale of any products relating to the ALPHA-1062 Technology;
  - 10% of any sublicensing revenue; and
  - 25% of an upfront payment or milestone payment paid by a sub-licensee to the Company;
- Upon completion of the Galantos Royalty Payments, a royalty payment to NLS of 1% of the revenue received from the ALPHA-1062 Technology by the Company over \$100 million per annum and
- The issuance of a promissory note of \$1,400,000 to NLS.

On January 1, 2016, the Company assumed NLS's obligations under a Royalty Agreement with Galantos Consulting dated August 31, 2013, which consisted of cumulative total payments to Galantos Consulting of €2,000,000, the cumulative total may be increased to €3,000,000 subject to certain provisions, which is to be paid as follows:

- 1% of the net sales revenue received by the Company from the sale of any products relating to the ALPHA-1062 Technology;
- 2% of any sublicensing revenue; and
- 2% of an upfront payment or milestone payment paid by a sub-licensee to the Company.

On March 6, 2023, the Company and NLS agreed to amend the License Agreement to now incorporate both Alpha Cognition Inc. and Alpha Cognition Canada Inc. under the License Agreement and added clarity to certain terms and definitions in the License Agreement.

### 2) ALPHA-0602 Technology

In November 2020, the Company entered into a license agreement with NLS for the world-wide exclusive right to the Progranulin ("ALPHA-602") Technology. In accordance with the agreement, the Company will pay the following:

- \$50,000 to NLS before January 15, 2021 (paid);
- a royalty of 1.5% of the commercial sales, capped at \$2,000,000, to NLS;
- 10% of any Upfront Payments in excess of \$2,000,000.

The total amount payable to NLS under this agreement shall not exceed \$2,000,000.

### 3) Spartan Capital Securities, LLC Agreement

On May 30, 2023, the Company agreed to enter into an ongoing consulting services agreement (the "Spartan Consulting Agreement") for a three year term with Spartan. The services include advising and assisting on potential business development transactions, strategic introductions, assisting management with enhancing corporate and shareholder value, and capital raising advice. Pursuant to the consulting services agreement the Company will pay Spartan a consulting fee in the aggregate amount of \$480,000, payable in three equal installments with each installment being subject to the Company achieving certain business development and capital raising objectives. Spartan will also be entitled to earn and receive additional Common Shares of the Company which will be issued to Spartan on a rolling basis upon completion of predetermined business development objectives including the closing of certain offering amounts and the completion of material business transactions. As of December 31, 2023, \$160,000 in consulting fees have been paid and no additional common shares had been issued under the consulting services agreement with Spartan.

On January 19, 2024, the Company paid the remaining \$320,000 consulting fee and issued 14,558,285 common shares to Spartan and its assignees pursuant to the Spartan Consulting Agreement.

## CONTINGENCIES

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The Company did not have any contingencies as at December 31, 2023 or the date of this report.

## TRANSACTIONS WITH RELATED PARTIES

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Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly. Key management personnel include the Company's executive officers and members of its Board of Directors.

In September 2018, the Company signed a management agreement with CMI Cornerstone Management Corp. ("CMI"), a company controlled by Ken Cawkell, the former CEO and a director of the Company, which required monthly payments of \$15,000. In June 2019, the Company amended the agreement to increase the monthly fees to \$18,000. Included in the agreement is a provision for a termination payment equal to the greater of (i) \$432,000 less any fees previously paid under the agreement between June 1, 2019 and the date of termination or (ii) \$54,000. On September 1, 2022, the Company amended the agreement to decrease the monthly fees to \$9,000. On April 30, 2023, the Company amended the agreement to an hourly fee of \$400 for services rendered. The amendment included a payment of \$54,000 for the termination fee.

In September 2018, the Company signed a management agreement with 9177 – 586 Quebec Inc., later assigned to 102388 P.E.I. Inc. ("PEI Inc."), companies controlled by Denis Kay, the Chief Scientific Officer of the Company, which required monthly payments of \$13,333 per month for an effective term of two years. In June 2019, the Company amended the agreement to increase the monthly fees to \$15,000. Included in the agreement is a provision for a termination payment equal to the greater of (i) \$360,000 less any fees previously paid under the agreement between June 1, 2019, and the date of termination or (ii) \$45,000. On August 15, 2022, the Company amended the agreement to decrease the monthly fees to \$7,500.

In August 2020, the Company signed a management agreement with Seatrend Strategy Group, ("Seatrend"), a company controlled by Jeremy Wright, the former CFO of the Company, which required monthly payments of \$6,000. In October 2020, the Company amended the agreement to increase the monthly fees to \$15,000. Included in the agreement is a provision for a termination payment of six's month's fees. On April 12, 2022, Jeremy Wright resigned as the CFO of the Company and was paid a termination payment of \$90,000.

In February 2021, the Company signed a consulting agreement with Michael McFadden, the CEO of the Company, requiring an annual base compensation of \$500,000. A new employment agreement was signed in March 2022 which included in the agreement is a provision for termination payment without just cause of:

- a) Severance payments for a period of twelve months with the following terms:
  - i) Months 1 through 6: 100% of annual base salary;
  - ii) Months 7 through 9: 50% of annual base salary; and
  - iii) Months 10 through 12: 25% of annual base salary.
- b) Bonus severance equal to the average of bonuses paid of the two most recent full fiscal years prior to termination plus the bonus that would have been paid in the fiscal year of termination.

Also included in the agreement is a provision for termination payment due to a change of control, the CEO will receive:

- a) a cash payment equal to the annual base salary;
- b) a full bonus payable in cash immediately, irrespective of whether targets have been met; and
- c) continuation of healthcare benefits for twelve months from date of change of control event.

In April 2022, Mr. McFadden was granted the ability to earn up to 8,195,740 bonus rights of which 1,639,148 bonus rights had been earned as at December 31, 2023.

In May 2021, the Company hired Lauren D'Angelo as the Company's Chief Commercial Officer. In 2023 Ms. D'Angelo was promoted to Chief Operating Officer of the Company. The employment agreement signed in May 2021 with Ms. D'Angelo requires an annual base compensation currently at \$420,000 and includes a provision for a termination payment due to a change of control as follows:

- a) a cash payment equal to the annual base salary;
- b) a full bonus payable in cash immediately, irrespective of whether targets have been met; and
- c) continuation of healthcare benefits for twelve months from date of change of control event.

In May 2022, Ms. D'Angelo was granted the ability to earn up to 1,065,446 bonus rights of which 737,616 bonus rights had been earned as at December 31, 2023.

In November 2021, the Company signed an employment agreement with Cedric O'Gorman, the Chief Medical Officer ("CMO") of the Company, requiring an annual base compensation of \$400,000. Included in the agreement is a provision for a termination payment without just cause of an amount equal to annual base compensation for a period of nine months. If termination is due to a change of control, the CMO will receive:

- a) a cash payment equal to the annual base salary;
- b) a cash bonus equal to 50% of the annual base salary; and
- c) continuation of healthcare benefits for twelve months from date of change of control event.

On January 1, 2023, Cedric O'Gorman resigned as the Chief Medical Officer of the Company.

In April 2022, the Company signed an employment agreement with Donald Kalkofen, the Chief Financial Officer ("CFO") of the Company, requiring an annual base compensation of \$420,000. Included in the agreement is a provision for termination payment due to a change of control, which if occurs, the CFO will receive:

- a cash payment equal to the annual base salary;
- a cash bonus equal to 50% of the annual base salary; and
- continuation of healthcare benefits for twelve months from date of change of control event.

During the year ended December 31, 2023, the Company entered into the following transactions with related parties:

- a) Incurred management fees of \$56,810 (2022 - \$220,508) and share-based compensation of \$217,527 (2022 - \$nil) to CMI. As at December 31, 2023, \$nil (2022 - \$54,000) was included in accounts payable and accrued liabilities owing to CMI.
- b) Incurred management fees of \$nil (2022 - \$140,409) to Seatrend.

- c) Incurred management fees included in research and development of \$56,984 (2022 - \$180,000) and share-based compensation included in research and development of \$15,351 (2022 - \$25,108) to PEI Inc. As at December 31, 2023, \$7,500 (2022 - \$41,250) was included in accounts payable and accrued liabilities owing to PEI Inc.
- d) Incurred share-based compensation of \$76,628 (2022 - \$123,148) to Len Mertz, a director of the Company.
- e) Incurred share-based compensation of \$62,773 (2022 - \$105,462) to John Havens, a director of the Company.
- f) Incurred share-based compensation of \$53,201 (2022 - \$93,671) to Philip Mertz, a director of the Company.
- g) Incurred share-based compensation of \$53,201 (2022 - \$93,671) to Rob Bakshi, a director of the Company.
- h) Incurred administrative fees of \$nil (2022 - \$9,555), included in other general and administrative expenses, to Cawkell Brodie LLP, a law firm where Mr. Cawkell was a managing partner.
- i) Incurred other research and development expenses of \$nil (2022 - \$10,500) and interest expense and accretion of \$50,196 (2022 - \$135,643) to NLS, a company related by common director. As at December 31, 2023, \$nil (2022 - \$11,001) was included in accounts payable and accrued liabilities owing to NLS and \$1,211,463 was owed for a promissory note.
- j) Incurred management fees and salaries of \$803,649 (2022 - \$499,860) and share-based compensation of \$836,020 (2022 - \$595,442) to Michael McFadden. As at December 31, 2023, \$250,000 (2022 - \$218,846) was included in accounts payable and accrued liabilities and \$58,427 (2022 - \$5,819) was included in other long-term liabilities to Mr. McFadden.
- k) Incurred management salaries included in research in development of \$638,136 (2022 - \$359,712) and share-based compensation included in research and development of \$503,073 (2022 - \$236,574) to Lauren D'Angelo, the Company's Chief Operating Officer. As at December 31, 2023, \$205,050 (2022 - \$150,151) was included in accounts payable and accrued liabilities and \$25,698 (2022 - \$2,476) was included in other long-term liabilities to Ms. D'Angelo.
- l) Incurred management salaries included in research and development of \$8,333 (2022 - \$400,000) and share-based compensation included in research and development of \$3,349 (2022 - \$172,377) to Cedric O'Gorman, the Company's former Chief Medical Officer.
- m) Incurred management fees and salaries of \$630,000 (2022 - \$305,594) and share-based compensation of \$530,158 (2022 - \$133,782) to Donald Kalkofen. As at December 31, 2023, \$210,000 (December 31, 2022 - \$155,114) was included in accounts payable and accrued liabilities for Mr. Kalkofen.

Summary of key management personnel compensation:

|                                                         | For the year ended<br>December 31, |                  |
|---------------------------------------------------------|------------------------------------|------------------|
|                                                         | 2023                               | 2022             |
|                                                         | \$                                 | \$               |
| Other general and administrative                        | -                                  | 9,555            |
| Other research and development                          | -                                  | 10,500           |
| Management fees and salaries                            | 1,490,459                          | 1,166,371        |
| Research and development - management fees and salaries | 703,453                            | 939,712          |
| Share-based compensation                                | 2,351,281                          | 1,576,235        |
|                                                         | <b>4,545,193</b>                   | <b>3,702,373</b> |

These expenditures were measured by amounts agreed upon by the transacting parties.

## FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

Financial instruments measured at fair value are classified into one of three levels in the fair value hierarchy according to the relative reliability of the inputs used to estimate the fair values. The three levels of the fair value hierarchy are:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly; and
- Level 3 – Unobservable inputs that are supported by little or no market activity, therefore requiring an entity to develop its own assumptions about the assumption that market participants would use in pricing.

The Company's financial instruments consist of cash, restricted cash, other current assets, loan receivable, accounts payable, bonus rights (presented in other long-term liabilities), derivative liability, and promissory note. The fair values of other current assets, loan receivable, accounts payable, and promissory note approximates their carrying values either due to their current nature or current market rates for similar instruments. Cash and restricted cash are measured at fair value on a recurring basis using level 1 inputs. Bonus rights and derivative liability are measured at fair value on a recurring basis using level 3 inputs. The continuity and valuation techniques that are used to determine the fair value of the other long-term liabilities and derivative liability are described in Notes 6 and 7 of the Interim Financial Statements.

The Company is exposed to a variety of financial risks by virtue of its activities including currency, credit, interest rate, and liquidity risk.

### a) Currency risk

Foreign currency exchange rate risk is the risk that the fair value or future cash flows will fluctuate as a result of changes in foreign exchange rates. The Company's operations are carried out in Canada and the United States. As at December 31, 2023, the Company had net monetary liabilities of approximately \$36,000 denominated in Canadian dollars. These factors expose the Company to foreign currency exchange rate risk, which could have an adverse effect on the profitability of the Company. A 10% change in the exchange rate with the Canadian dollar would change net loss and comprehensive loss by approximately \$2,700. At this time, the Company currently does not have plans to enter into foreign currency future contracts to mitigate this risk, however it may do so in the future.

## b) Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation.

The Company's cash is held in a large Canadian financial institution and a United States of America based financial institution. Additionally, as at December 31, 2023, the Company had \$475,567 in cash held at its payment processing company in a demand account to be used to pay accounts payable. The Company maintains certain cash deposits with Schedule I financial institutions, which from time to time may exceed federally insured limits. The Company has not experienced any significant credit losses and believes it is not exposed to any significant credit risk. The Company's tax recoverable is due from the Government of Canada; therefore, the credit risk exposure is low. The Company's maximum credit risk is equal to the carrying value of cash, restricted cash, loan receivable and other current assets at December 31, 2023 and 2022.

## c) Interest rate risk

Interest rate risk is the risk the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Financial assets and liabilities with variable interest rates expose the Company to interest rate cash flow risk. The Company does not hold any financial liabilities with variable interest rates. Financial assets and liabilities with fixed interest rates expose the Company to interest rate price risk. As at December 31, 2023, the promissory note bears interest of 5.5% per annum and is subject to interest rate price risk. The Company maintains bank accounts which earn interest at variable rates but it does not believe it is currently subject to any significant interest rate risk.

## d) Liquidity risk

The Company's ability to continue as a going concern is dependent on management's ability to raise required funding through future equity issuances and through short-term borrowing. The Company manages its liquidity risk by forecasting cash flows from operations and anticipating any investing and financing activities. Management and the Board of Directors are actively involved in the review, planning and approval of significant expenditures and commitments. As at December 31, 2023, the Company had working capital deficit of \$706,463.

Contractual undiscounted cash flow requirements for financial liabilities as at December 31, 2023 are as follows:

|                  | ≤1 Year   | >1 Year | Total     |
|------------------|-----------|---------|-----------|
|                  | \$        | \$      | \$        |
| Accounts payable | 1,394,117 | -       | 1,394,117 |
| Promissory note  | 1,211,463 |         | 1,211,463 |
|                  | 2,605,580 |         | 2,605,580 |

## **OTHER RISKS AND UNCERTAINTIES**

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The business and operations of the Company is subject to a number of risks of which you should be aware before making a decision to invest in our common stock., many of which are beyond the Company's control. The Company considers the risks set out below to be some of the most significant to potential investors in the Company, but not all of the risks are associated with an investment in securities of the Company. If any of these risks materialize into actual events or circumstances or other possible additional risks and uncertainties of which the Company is currently unaware or which it considers to be material in relation to the Company's business actually occur, the Company's assets, liabilities, financial condition, results of operations (including future results of operations), business and business prospects, are likely to be materially and adversely affected. In such circumstances, the price of the Company's securities could decline and investors may lose all or part of their investment. For a complete list of the Company's Risk Factors, please refer to our "Annual Information Form" filed on Sedarplus.ca on June 26, 2023.

### **Risks Relating to the Loss of Foreign Private Issuer Status**

Effective January 1, 2023 we no longer qualified as a Foreign Private Issuer under US securities laws and as such are subject to the U.S. securities laws as applicable to U.S. domestic companies.

The Company has determined that it ceased to qualify as a "foreign private issuer" ("FPI"), as such term is defined in Rule 405 under the Securities Act and Rule 3b-4 under the United States Securities Exchange Act of 1934 (the "Exchange Act"), as of September 30, 2022, being the last business day of our most recently completed second fiscal quarter. As a result, commencing January 1, 2023, the Company is no longer eligible to rely on relief of certain requirements under the Exchange Act available to FPIs, and as such securities issued by the Company will no longer qualify for resale outside of the United States under Rule 904 of Regulation S without a restrictive legend applying. As a result, commencing January 1, 2023, investors acquitting securities of the Company will not be able to rely on such rule to sell Securities outside of the United States in advance of the restrictions under Rule 144 under the Securities Act being removed, which typically results in a 12 month restriction on the ability of the holder to resell such Securities. Once an issuer fails to qualify for foreign private issuer status it will remain unqualified unless it subsequently meets the requirements for foreign private issuer status as at the last business day of its second fiscal quarter. If the Company subsequently qualifies as a foreign private issuer on the last business day of a subsequent second fiscal quarter, the Company will immediately be able to rely on provisions under US securities laws applicable to foreign private issuers.

### **Financing risks**

Our operations have required substantial amounts of capital since inception, and we expect our expenses to increase significantly in the foreseeable future. Identifying preparing for commercialization of our lead asset ALPHA-1062, potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we seek marketing approval for ALPHA-1062 for mild-to-moderate Alzheimer's disease, prepare for commercialization activities, complete our ongoing clinical trials of our product candidates, initiate future clinical trials of our product candidates, and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success.

As of December 31, 2023, we had \$1,494,573 in cash and cash equivalents including \$90,413 in restricted cash and have not generated positive cash flows from operations. We will need to raise additional capital. Additional capital may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by recent volatility in the equity markets in Canada, the United States and worldwide. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

### **History of operating losses and negative cash flow from operating activities**

The Company has reported negative cash flow from operating activities since inception and expects to experience negative operating cash flows for the foreseeable future. The operating losses will continue as significant costs will be incurred to seek marketing approval for ALPHA-1062 for mild-to-moderate Alzheimer's disease, prepare for commercialization activities, further the clinical development of ALPHA-1062 and development of the PGRN Technology. Until any approval from the FDA and other regulatory authorities for the sale of ALPHA-1062, the Company's working capital requirements are dependent on the Company's ability to raise capital by future issuances of common shares, debt instruments or other securities convertible into common shares or through potential partnership or strategic financing opportunities, if any become available at terms that are acceptable to the Company. In addition, unfavorable global economic or political conditions could adversely affect our ability to raise additional capital, business, financial condition or results of operations.

### **Our business is heavily dependent on the successful development, regulatory approval and commercialization of ALPHA-1062 and any future product candidates that we may develop or acquire.**

The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, the FDA approval and commercialization of ALPHA-1062, currently our only clinical-stage product candidate. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The clinical and commercial success of ALPHA-1062 and any future product candidates that we may develop or acquire will depend on a number of factors, including the following:

- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved; and
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates.

### **Research and development risk**

The Company's organic growth and long-term success is dependent in part on its ability to successfully develop products and it will likely incur significant research and development expenditures to do so. The Company cannot be certain that any investment in research and development will yield technically feasible or commercially viable products. Furthermore, its ability to discover and develop products will depend on its ability to:

- retain key scientists as employees, consultants or partners;
- develop products internally and assist its partners with development;
- successfully complete laboratory testing and clinical trials on humans;
- obtain and maintain necessary intellectual property rights to the Company's products;
- obtain and maintain necessary U.S. and other regulatory approvals for its products;
- collaborate with third parties to assist in the development of its products; and
- enter into arrangements with third parties to co-develop, license, and commercialize its products.

The Company may not be successful in developing its drug products. Failure to introduce and advance current and new products could materially and adversely affect the Company's operations and financial condition.

### **Risks Related to Commercialization and Manufacturing**

- Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of adoption and use by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.
- We may find that the market opportunities for ALPHA-1062, if approved, may be smaller than we anticipate.
- We rely on third-party suppliers to manufacture our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business, financial condition, results of operations and prospects.
- We are subject to certain supply chain risks inherent in manufacturing our lead product, ALPHA-1062, and future products with respect to Taiwan. Risks including periodic foreign economic downturns and political instability, which may adversely affect the company's ability to obtain materials and conduct business in Taiwan.
- Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process that is more efficient and cost-effective to commercialize our potential products, which may not be successful.
- The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those drugs and decrease our ability to generate revenue.
- We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

### **If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved.**

In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build or partner marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

### **Clinical development risks**

The Company must demonstrate the safety and efficacy of their products through extensive clinical testing. The Company's drug research and development programs are various stages of development including early stage of development. Numerous unforeseen events during, or as a result of, the testing process could delay

or prevent required FDA and regulatory approvals and thus future commercialization of any products the Company develops, including the following:

- the results of clinical studies may be inconclusive, may demonstrate potentially unsafe drug characteristics, or may not be indicative of results that will be obtained in later clinical trials;
- the safety and efficacy results attained in the clinical studies may not be indicative of results that are obtained in later clinical trials;
- after reviewing clinical study results, the Company or its partners or collaborators may abandon projects that were previously thought to be promising.

Clinical studies are very expensive, can run into unexpected difficulties and the outcomes are uncertain. The final data collected from studies the Company conducts may not be sufficient to support the further clinical development of ultimately regulatory approval of such product(s). Clinical studies of the Company's products may not be completed on schedule or on budget, with available capital resources. The Company's failure to complete any of its clinical studies on schedule or on budget, or its failure to adequately demonstrate the safety and efficacy of any of the products it develops, could delay or prevent regulatory approval of such products, which could adversely affect the Company's business, financial condition, and results of operations.

**Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of adoption and use by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.**

Even if one or more of our product candidates receive FDA or other regulatory approvals, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from governmental healthcare plans or third party payors for any of our product candidates that may be approved;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies; and
- limitations or warnings contained in the FDA-approved labeling for our products.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians, patients, healthcare payors and others in the medical community. Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be more effective than other commercially available alternatives or successfully commercialized. Any approval we may obtain could be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a REMS. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our reputation, ability to raise additional capital, financial condition, results of operations and business prospects.

**The FDA approval process is rigorous, and there is no guarantee that a new drug will be approved.**

The FDA approval process is rigorous, and there is no guarantee that a new drug will be approved. Any delays or denials in the approval process can impact the Company's operating expenditures, future revenues and reputation. Clinical trials are a critical component of the NDA filing process, and any issues related to the quality or quantity of clinical trial data can delay or impact FDA approval. Inadequate data may also lead to questions around the safety and efficacy of the drug. The NDA filing process involves numerous regulations, and any failure to comply with them can result in legal and financial penalties, as well as damage to the Company's reputation. It is critical for biopharma companies to ensure that their NDA filings are accurate, complete, and comply with all regulatory requirements. The NDA filing process requires the disclosure of proprietary information, including data from clinical trials and manufacturing processes. Any unauthorized disclosure of this information can harm the Company's potential revenue and reputation. The biopharma industry is highly competitive, and any delay in FDA approval or failure to obtain approval can give competitors an advantage. Additionally, the approval of similar drugs can impact the market potential for a new drug. The NDA filing process involves the manufacturing and distribution of pharmaceutical products. Any issues related to the manufacturing process or disruptions in the supply chain can impact the quality, safety, and efficacy of pharmaceutical products, leading to product recalls or delays in commercialization.

**The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide an adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.**

Manufacturing drugs, especially in large quantities, as needed for commercialization and clinical trials, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or product recalls. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable quality and efficacy of the products before and after such changes. If our third-party manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

**We rely on third-party suppliers to manufacture our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business, financial condition, results of operations and prospects.**

We do not currently have, nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates are subject to various regulatory requirements and may be subject to inspection from the FDA or other regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our product candidates and we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our lead product candidate involves several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product

manufacturing. We have a direct relationship with a manufacturer in Taiwan for our lead candidate, ALPHA-1062. As a result, the supply chain for the manufacturing of our product candidates is complicated, and we expect the logistical challenges associated with our supply chain to grow more complex as our product candidates are further developed.

**Our success depends on our ability to obtain and maintain patent protection for our technology and product candidates including our lead product candidate, ALPHA-1062. If such protection is not obtained, the scope of the patent protection obtained is not sufficiently broad, or we lose such protection, we may not be able to compete effectively in our markets.**

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our technology and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future drug development programs and product candidates, successfully defend our intellectual property rights against third-party challenges and successfully enforce our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patents and patent applications that we own may fail to result in issued patents with claims that protect any of our product candidates in the United States or in other foreign countries. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage.

### **Risks Related to Our Industry**

- Research and development of pharmaceuticals is lengthy and inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval.
- Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.
- Failure to comply with health and data protection laws and regulations could lead to government enforcement actions and civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.
- Even if the product candidates that we develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for our product candidates and adversely affect our business.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

### **Risks Related to Government Regulation**

- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable.
- Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.
- Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

- Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

**Our plans to out-license TBI related program may not succeed.**

The Company expects to out-license the limited use of ALPHA-1062 solely for applications in treating mTBI and TBI to Alpha Seven. The establishment and funding of Alpha Seven are at the proposal stage only. There is no guarantee that the Company will be successful at launching Alpha Seven as a separately funded entity, or at all. If successfully launched, there is no guarantee that Alpha Seven will be successful in advancing the ALPHA-1062/IN for use in TBI or mTBI.

The Company's ability to out-license its technology or intellectual property may be limited by the strength and enforceability of its intellectual property rights, as well as the willingness of potential licensees to pay for such rights. The Company may be unable to obtain or enforce patent protection for its technology, which could limit its ability to out-license the technology to Alpha Seven. In addition, the Company's competitors may challenge the validity or enforceability of its patents or other intellectual property rights, which could result in costly legal proceedings that may adversely affect the Company's financial condition or its ability to out-license its technology to Alpha Seven. Even if the Company is able to out-license its technology or intellectual property to Alpha Seven, it may not receive the expected financial benefits or other advantages from such arrangements and may face competition from other technologies or companies. The failure to successfully out-license the technology or intellectual property to Alpha Seven could have a material adverse effect on the Company's financial condition, results of operations, and prospects.

**If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected.**

We are highly dependent upon members of our senior management, particularly our Chief Executive Officer, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates or any future product candidates. 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 our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

**If we sell our Common Shares in future financings, shareholders may experience immediate dilution and, as a result, our stock price may decline.**

Because we expect our expenses to increase significantly in the foreseeable future and because, based on our current business plans, we believe that any net proceeds from future financings, together with our existing cash, cash equivalents and marketable securities, will be insufficient for us to fund our planned, commercialization, operating and capital expenditures over the next year, we may from time to time issue additional Common Shares. These issuances may be at a discount from the current trading price of our Common Shares. As a result, our shareholders would experience immediate dilution upon the purchase of any Common Shares sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities or Common Shares. If we issue Common Shares or securities convertible into Common Shares, our shareholders will experience additional dilution and, as a result, our stock price may decline.

## **ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED**

Accounting standards or amendments to existing accounting standards that have been issued but have future effective dates are either not applicable or are not expected to have a significant impact on the Company's consolidated financial statements.

As part of the new amendments, the Company adopted Disclosure of Accounting Policies (Amendments to IAS 1 and IFRS Practice Statement 2) from January 1, 2023. Although the amendments did not result in any changes to the accounting policies themselves, they impacted the accounting policy information disclosed in the financial statements. The amendments require the disclosure of 'material', rather than 'significant', accounting policies. The amendments also provide guidance on the application of materiality to disclosure of accounting policies, assisting entities to provide useful, entity-specific accounting policy information that users need to understand other information in the financial statements. Management reviewed the accounting policies and made updates to the information disclosed in certain instances in line with the amendments.

## **DISCLOSURE OF CONTROLS AND PROCEDURES AND INTERNAL CONTROL OVER FINANCIAL REPORTING**

The CFO, together with other members of management, have designed the Company's disclosure controls and procedures in order to provide reasonable assurance that material information relating to the Company and its consolidated subsidiaries would be known to them, and by others, within those entities.

Management has also designed internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with IFRS. Management has assessed the effectiveness of the Company's internal control over financial reporting as of the year ended December 31, 2023.

While the officers of the Company have designed the Company's disclosure controls and procedures and internal controls over financial reporting, they expect that these controls and procedures may not prevent all errors and fraud. A control system, no matter how well conceived or operated, can only provide reasonable, not absolute assurance that the objectives of the control system are met.

## **DISCLOSURE DATA FOR OUTSTANDING COMMON SHARES, OPTIONS, AND WARRANTS**

The Company is authorized to issue the following share capital:

- Unlimited common voting shares without par value ("Common Shares")
- Unlimited Class A restricted voting shares without par value ("Restricted Shares")
- Unlimited Class B preferred Series A shares without par value ("Class B Preferred Shares")

Below is a summary of the shares, stock options, and share purchase warrants issued and outstanding as at December 31, 2023 and the date of this report:

|                                       | <b>December 31,<br/>2023</b> | <b>Date of this<br/>Report</b> |
|---------------------------------------|------------------------------|--------------------------------|
| Common Shares                         | 118,208,989                  | 149,925,536                    |
| Class B Preferred Shares              | 7,916,380                    | 7,916,380                      |
| Common Share options                  | 20,672,207                   | 20,399,367                     |
| ACI Canada legacy performance options | 6,821,057                    | 6,821,057                      |
| Warrants                              | 43,729,794                   | 61,732,886                     |

**Common Share options**

The Company has issued incentive options to certain directors, officers, and consultants of the Company. As of the date of this report, the following Common Share options are outstanding and exercisable:

| <b>Options Outstanding</b> | <b>Options Exercisable</b> | <b>Exercise Price</b> | <b>Expiry Date</b> |
|----------------------------|----------------------------|-----------------------|--------------------|
| 39,154                     | 39,154                     | 0.40                  | June 1, 2029       |
| 39,154                     | 39,154                     | 0.40                  | July 22, 2030      |
| 2,600,000                  | 2,022,222                  | 0.21 (CAD\$0.28)      | August 3, 2031     |
| 940,000                    | 940,000                    | 0.21 (CAD\$0.28)      | December 20, 2031  |
| 215,000                    | 125,419                    | 0.21 (CAD\$0.28)      | February 14, 2032  |
| 450,000                    | 262,500                    | 0.21 (CAD\$0.28)      | April 11, 2032     |
| 450,000                    | 340,278                    | 0.21 (CAD\$0.28)      | May 31, 2032       |
| 15,666,059                 | 5,926,765                  | 0.17 (CAD\$0.22)      | June 8, 2033       |
| <b>20,399,367</b>          | <b>9,695,492</b>           |                       |                    |

**ACI Canada legacy performance options**

The Company has issued incentive options to certain directors, officers, and consultants of the Company. As of the date of this report, the following share options are outstanding and exercisable:

| <b>Options Outstanding</b> | <b>Options Exercisable</b> | <b>Exercise Price</b> | <b>Expiry Date</b> |
|----------------------------|----------------------------|-----------------------|--------------------|
|                            |                            | \$                    |                    |
| 900,000                    | 900,000                    | 0.001                 | February 1, 2026   |
| 691,057                    | 691,057                    | 0.01                  | December 31, 2027  |
| 3,050,000                  | 2,830,000                  | 0.01                  | September 1, 2028  |
| 2,180,000                  | 1,980,000                  | 0.01                  | June 1, 2029       |
| <b>6,821,057</b>           | <b>6,401,057</b>           |                       |                    |

**Warrants**

A summary of the share purchase warrants outstanding as at the date of this report is as follows:

| <b>Warrants Outstanding</b> | <b>Exercise Price</b> | <b>Expiry Date</b> |
|-----------------------------|-----------------------|--------------------|
|                             | \$                    |                    |
| 3,061,783                   | 0.40                  | August 30, 2024    |
| 3,329,828                   | 0.31                  | August 31, 2026    |
| 876,595                     | 0.31                  | October 16, 2026   |
| 2,524,993                   | 0.31                  | November 8, 2026   |
| 9,864,305                   | 0.31                  | December 22, 2026  |
| 18,003,092                  | 0.31                  | January 19, 2027   |
| 2,155,000                   | 0.29 (CAD\$0.39)      | February 16, 2028  |
| 14,640,221                  | 0.283                 | February 16, 2028  |
| 719,904                     | 0.29 (CAD\$0.39)      | March 15, 2028     |
| 6,557,165                   | 0.289                 | March 15, 2028     |
| <b>61,732,886</b>           |                       |                    |

## **OTHER MD&A REQUIREMENTS**

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Additional information relating to the Company may be found on or in:

- SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca); and
- the Company's audited consolidated financial statements for the years ended December 31, 2023 and 2022.

This MD&A was approved by the Board of Directors of Alpha Cognition Inc. effective April 3, 2024.