

# ALPHA COGNITION INC.

Management's Discussion and Analysis For the three and six months ended June 30, 2022

(Expressed in United States Dollars)

#### MANAGEMENT'S DISCUSSION AND ANALYSIS

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 three and six months ended June 30, 2022. The following information should be read in conjunction with the accompanying audited financial statements and accompanying notes for the years ended December 31, 2021 and 2020 ("Annual Financial Statements") and the unaudited condensed interim consolidated financial statements and accompanying notes for the three and six months ended June 30, 2022 and 2021 ("Interim 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 unless otherwise noted. Additional information relating to the Company is available on SEDAR at www.sedar.com.

## FORWARD-LOOKING STATEMENTS

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 August 25, 2022.

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 <a href="www.sedar.com">www.sedar.com</a> and readers are urged to review these materials.

## **COMPANY DESCRIPTION**

ACI is the parent company of Alpha Cognition Canada Inc. ("ACI Canada"). The Company is a clinical stage, biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's disease (AD) and Amyotrophic Lateral Sclerosis (ALS), for which there are limited treatment options.

ALPHA-1062, is a patented new chemical entity being developed as a new generation acetylcholinesterase inhibitor for the treatment of Alzheimer's disease ("AD"), 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 also being developed in combination with memantine to treat moderate to severe Alzheimer's dementia and as an intranasal formulation for traumatic brain injury.

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.

On March 18, 2021, the Company announced the successful closing of a business combination with ACI Canada (the "Transaction"). Pursuant to the Transaction, ACI Canada was acquired by and became a wholly-owned subsidiary of ACI. As part of the Transaction, on March 18, 2021, the Company changed its name to Alpha Cognition Inc. and ACI Canada changed its name to Alpha Cognition Canada Inc. The common shares of the Company are currently listed on TSX-V under the ticker symbol "ACOG".

Upon closing of the Transaction, the shareholders of ACI Canada owned 97.23% of the shares of the Company, and as a result, the transaction is considered a reverse acquisition of the Company by ACI Canada. All previous common shares, share options, and warrants were exchanged at a ratio of one share of ACI Canada for one of ACI. For accounting purposes, ACI Canada is considered the acquirer of the Company accordingly, the consolidated financial statements are in the name of Alpha Cognition Inc.; however, they are a continuation of the financial statements of ACI Canada (Refer to Reverse Acquisition section).

## **GOING CONCERN AND ADDITIONAL CAPITAL REQUIRED**

The Company has not generated revenues from its operations to date and as at June 30, 2022, had a deficit of \$43,951,060 (December 31, 2021 - \$38,033,903) which has been primarily financed by equity. The Company had \$5,975,457 in Cash and \$2,001,397 in current liabilities as of June 30, 2022. The Company's continuing operations, as intended, are highly dependent upon its ability to generate cash flows or obtain additional financing. 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 in the following discussion. Management recognizes it will need to raise addition financing to cover planned development and operating costs in the coming months. 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.

During the third quarter of 2022 the Company initiated cost cutting measures to look to extend the cash runway and reduce ongoing cash burn. The Company streamlined R&D programs and will prioritize spend the NDA filing and support for ALPHA-1062. The Company has also reduced headcount and other operating costs not essential to the ALPHA-1062 NDA file. The company lowered its near term quarterly burn until 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 current research and development. Any of these actions could have a material adverse effect on our business, results of operations or financial condition.

## **ALPHA-1062**

ALPHA-1062 is a patented new chemical entity. When absorbed through mucosal tissue or ingested it is enzymatically converted to an active moiety that has previously been approved by the U.S. 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, prior to conversion and during the absorption and the ingestion process, may have reduced gastrointestinal side effects which could result in reduced up-titration periods and may facilitate dosing at therapeutic 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 a nasal formulation had been developed, subsequently oral dosage formulations have been developed.

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 from existing acetylcholinesterase inhibitor (AChEI) treatments, with the exception of galantamine's mechanism of action.
- Regulatory Development: Demonstrate that a New Drug Application ("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 Clinical Development

The original nasal formulation of ALPHA-1062 was used to conduct Phase I human studies, initially by Neurodyn Life Sciences Inc. ("NLS"), 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 aged patients 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 began planning and preparation for the pivotal trial of an oral dosage form of ALPHA-1062 in Q3, 2021, and successfully completed the study in Q2 2022. The study was designed to demonstrate pharmacokinetic equivalence compared to the reference listed drug galantamine hydrobromide, which is a standard of care treatment for patients with mild to moderate AD. Topline results confirmed in fed and fasted bioequivalence studies that ALPHA-1062 achieved bioequivalent area-under-the-curve and peak exposures relative to galantamine hydrobromide IR. Data were within the required pharmacokinetic range of prior data demonstrated with galantamine hydrobromide ER. There were no adverse events reported for ALPHA-1062 during these studies. With these positive pivotal study results, Alpha Cognition plans to file an NDA for ALPHA-1062 in mild to moderate AD in Q2 2023, with possible FDA approval for the US market by Q1 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**

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
AUC0-inf (μg × h/mL) Fasted State	306.8	321.5	95%	1
Cmax (ng/mL) Fasted State	30.7	40.5	76%	1
AUC0-inf (μg × h/mL) Fed State	286.7	329.9	87%	1
Cmax (ng/mL) Fed State	27.6	30.2	91%	1

#### **BABE Study vs. Extended Release**

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
AUC0-24 (μg × h/mL) Steady State	527.5	492.1	107%	1
Cmax (ng/mL) Steady State	41.7	32.8	127%	1

- 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 singledose of ALPHA-1062 (or galantamine benzoate) 5mg delayed release tablet compared to galantamine hydrobromide tablet 4mg immediate release - the reference drug. 36 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 tells you 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 average 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 Cmax ratio to reference drug for ALPHA-1062 was 76% (30.7) in the fasted study and 91% (27.6) in the fed study both Cmax results being higher than the published Cmax 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 Cmax 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 Cmax compared to galantamine hydrobromide in the fed state. When the Cmax of a proposed drug product falls between the reported Cmax 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. There were two adverse events associated with administration of the reference drug galantamine hydrobromide - diarrhea and vomiting, in keeping with the known side effect profile for that medication.

#### 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 (ER) capsules, when dosed to steady state. Bioequivalence was established based on total drug exposure (AUC) and the Cmax 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 AD, planned for Q2 2023.

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 ER. In the pre-specified primary analysis, ALPHA-1062 achieved area-under-the-curve and peak exposures of approximately 107% and 127%, respectively, compared to those generated by galantamine hydrobromide ER. As expected, Cmax results for ALPHA-1062 is bracketed between galantamine hydrobromide IR and ER (lower than IR, higher than ER) 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 now plans to file its NDA for ALPHA-1062 in mild-to-moderate Alzheimer's Disease in Q2 2023, allowing the company to include additional CMC stability data in the NDA filing. The company's projected commercial launch date of Q1 2024 remains the same.

RESOLVE Tolerability Study: The Company plans to initiate an Alzheimer's disease tolerability and dosing trial with ALPHA-1062 called the RESOLVE Study which could potentially support prescribing information changes, post-approval, and could allow patients to achieve an efficacious dose more quickly than with current treatments. Significant start-up activity has already been completed. Processes have been put in place, data management support has been engaged, and a number of sites have been identified, evaluated, qualified and readied for activation. IRB approval has been received and the final study protocol has been submitted to the IND. The Company is seeking capital required to support the study initiation and if/when successful in securing the capital would look to commence enrollment into this study within a quarter of securing capital.

Mild Traumatic Brain Injury (mTBI): The Company has also completed a pre-clinical study of a nasal formulation of ALPHA-1062 in mTBI. The Company is encouraged by the preclinical data and is planning to request a meeting with the FDA to discuss IND submission and further clinical development plans.

In December 2021, the Company announced functional data from the ALPHA-1062 Traumatic Brain Injury (TBI) program. ALPHA-1062 intranasal administration significantly reduced the extent of the functional deficit, and improved functional recovery of TBI animals compared to untreated animals suffering a TBI. Notably, in four of five functional measures of recovery, the performance of the ALPHA-1062 treated group was statistically indistinguishable from that of the uninjured cohort.

In a rodent model of TBI, ALPHA-1062 or vehicle (purified water as treatment control) was administered intranasally, with treatment initiated 2 hours after injury and continued twice daily for 35 days. ALPHA-1062 significantly:

- Acutely limited the extent of motor deficit.
- Improved motor and sensory functional recovery measured by motor skill assessment, sensory/motor skill assessment, and Modified Neurological Severity Score which comprises motor, sensory, balance and reflex assessment.

 Improved cognitive functional recovery measured by tests which assess recognition memory, and spatial learning and memory.

In February 2022 the Company announced histology data from their intranasal ALPHA-1062 Traumatic Brain Injury (TBI) program. ALPHA-1062 treatment was neuroprotective, preserving hippocampal structure, reducing cell loss and promoting neurogenesis compared to no treatment. These histological results, confirm the functional preservation/recovery data, and taken together, strongly support the further development of ALPHA-1062 for the treatment of TBI.

Compared to vehicle, ALPHA-1062 treatment:

- Demonstrated statistically significant reduction in lesion size measured at 35 days after injury.
- Preserved greater hippocampal structure. The hippocampus plays a critical role in learning, memory formation, and spatial coding and damage to hippocampus can lead to memory disorders like AD, amnesia, and depression.
- Demonstrated statistically, significant reduction in neuronal cell loss. The number of neurons in the ALPHA-1062 treated animals were equivalent to those in the uninjured cohort of animals at the end of treatment.
- Statistically significantly enhanced neurogenesis as evidence by an increase in the number of neuron
  precursor cells and new neurons in the dentate gyrus, which plays a critical role in learning, information
  processing, and mood regulation.

# ALPHA - 1062 Commercialization Strategy

During the second half of 2021 the Company started, in parallel with the Company's regulatory activities, taking steps to develop a commercialization team to manage product manufacturing and distribution. 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 Neurology and Long Term Care (LTC) physicians in the US. Neurologists that specialize in Alzheimer's treatment make pharmacologic decisions for Alzheimer's patients in a clinical setting. 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 US from these two specialties is large, with over 11 million prescriptions filled in pharmacies each year. AChEl drugs include Aricept, Exelon, Exelon Patch, Razadyne, and generic versions of each brand. 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 by the end of year 1. The Company believes that patients who discontinue a first therapy will try a 2<sup>nd</sup> line 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 make potential key points of label differentiation and exploit key issues with existing AChEI medications. Success will be further enabled by deploying a highly targeted and efficient multi-channel marketing campaign, by motivating caregivers to request ALPHA-1062, and securing product coverage with US payors. Market research indicates that payors are likely to cover ALPHA-1062 if the product is competitively priced. Additionally, Alpha Cognition intends to seek strategic partnerships to expand promotional efforts and expand 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.

#### **ALPHA-0602**

The ALPHA-0602 product candidate originated almost a decade ago when it was discovered by researchers at McGill University in Montreal that a protein called Progranulin seemed to show activity for several neurological disorders. Progranulin is a large protein that was found to be present in virtually all living animals and appears to be used by the body for multiple tasks. Upon further investigation, scientists discovered that the large molecule was made of smaller polypeptides or subunits, referred to as Granulin Epithelin Modules ("GEMs").

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord that carry messages from the brain to the muscles (Source: Laird et al. (2010), Chitramuthu et al. (2017)) A safe and effective treatment for ALS remains an unmet medical need. The few treatment options that currently exist for ALS patients, have shown limited effectiveness. ALPHA-0602 is being developed for the treatment of ALS and has been granted Orphan Designation by the U.S. FDA.

During the second quarter of 2022 the company received Rare Pediatric Designation for ALPHA-0602 for treatment of spinal muscular atrophy. This designation allows for priority review.

#### ALPHA-0602, ALPHA-0702 & ALPHA-0802 Pre-Clinical Development

ALPHA-0602 has been investigated in preclinical studies designed to stimulate the overproduction of progranulin in validated animal models of neurological disorders, specifically ALS. Initial work with animal models of ALS has been completed indicating that Progranulin may be effective in modifying the disease process. Additional in-vitro and in-vivo investigations to validate the effectiveness of Progranulin and the potential of the GEMs are ongoing.

In March 2022 the Company announced positive preclinical data from its ALPHA-0602 ALS gene therapy program. These data underscore the robust preclinical evidence supporting Alpha Cognition's gene therapy approach to treating ALS and highlight the Company's strategy to validate these data in planned clinical trials.

Highlights of the positive proof of concept pre-clinical results demonstrated with ALPHA-0602 in vitro in motor neurons and in vivo in models of ALS, include:

- ALPHA-0602 demonstrated abundant PGRN expression in motor neurons, suggesting a neurotrophic role for PGRN. ALPHA-0602 further increased PGRN levels and decreased motor neuron cell death in in vitro models.
- Using an in vivo model of ALS to further assess the neurotrophic effects of PGRN, ALPHA-0602 reversed the motor neuron toxicity resulting from both decreased levels of TDP-43 and FUS, and the expression of ALS related toxic forms of these proteins.
- In an ALS transgenic mouse model caused by a toxic form of TDP-43, Alpha-0602 administered via adeno-associated virus, resulted in successful viral transduction of CNS cells and substantially increased cerebrospinal fluid (CSF) levels of PGRN.
- ALPHA-0602 treated TDP-43 transgenic mice persistently gained weight throughout the 10-week study, in contrast to untreated transgenic animals who failed to gain weight. Continued weight gain in the face of a significant and sustained toxic insult, is suggestive of a therapeutic benefit of Alpha-0602 expression.

In June 2022, the Company announced the discovery of two GEM combinations, ALPHA-0702 and ALPHA-0802, and positive preclinical data from each candidate therapy. ALPHA-0702 and ALPHA-0802 are Granulin Epithelin Motifs, or GEMs, derived from full length progranulin (PGRN) 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 have demonstrated robust results in a recent preclinical study, leading the Company to believe in the future potential of this platform to develop therapeutics to treat a wide array of diseases. These data underscore robust preclinical evidence supporting Alpha Cognition's approach to treating neurodegenerative disease and highlight the Company's strategy to validate these data in additional pre-clinical studies.

Highlights of the positive proof of concept pre-clinical results demonstrated with ALPHA-0702, ALPHA-0802, and ALPHA-0602 include:

- ALPHA-0702 and ALPHA-0802 maintained prolonged cell survival and neuronal morphology, with a potency equivalent to, or approaching full length progranulin.
- ALPHA-0702 and ALPHA-0802 reduced both mutant and wild type TDP-43 toxicity, with a potency
  equivalent to, or approaching full length progranulin.

- ALPHA-0602, and both ALPHA-0702 and ALPHA-0802 enhanced Cathepsin D maturation suggestive
  of improved lysosomal function. These effects were seen in induced pluripotent stem cells, derived
  from patients harboring toxic TDP-43 mutations, that were terminally differentiated into motor neurons.
  Both therapeutic candidates have the potential to be as effective as full-length progranulin in promoting
  Cathepsin D maturation, where under conditions of neuronal stress (FTD models) progranulin has
  been shown to be inappropriately processed.
- Ongoing studies will confirm reduced neuroinflammation and toxicity associated with ALPHA compounds.

## ALPHA-0602 Regulatory Development

The in-vitro and preclinical program to select the lead biological drug candidates was completed in Q2 2022, with final confirmatory activity being completed in Q3 2022. The Company intends to seek FDA input on the, relevant pre-clinical safety studies to be initiated in animal models consistent with US FDA requirements to support an Investigational New Drug Application. The lead drug candidate would follow a conventional Biologics License Application ("BLA") approval process requiring Phase I – III clinical trials to support the use of progranulin for use in treating ALS.

In February 2020, ALPHA-0602 was granted Orphan Drug Designation by the FDA for the use of ALPHA-0602 in the treatment of ALS. The Orphan Drug Designation has several significant benefits including:

- (1) tax credits of 50% off the clinical drug testing cost awarded upon approval;
- (2) eligibility for market exclusivity for seven years post approval; and
- (3) waiver of NDA and biologics license application fees, which could amount to approximately US\$2,200,000.

The company has received Rare pediatric designation for ALPHA-0602 for treatment of spinal muscular atrophy. This voucher be either redeemed by the sponsor of the rare pediatric disease designated product to expedite the review of subsequent NDA or BLA or sold to another sponsor for use in the same manner.

# **Current Year Summary**

In January 2022, the Company issued 21,008 Common shares for the exercise of 21,008 Common shares options at a price of CAD\$0.714 per share for total proceeds of \$11,851 (CAD\$15,000).

In February 2022, the Company granted 230,000 share options to certain employees of the Company with an exercise price of CAD\$1.05 per share. The options will be subject to the following vesting terms: 25% will vest on February 14, 2023 and the remaining 75% will vest in equal monthly instalments until February 14, 2025.

In February 2022, the Company issued 350,000 Common shares for the exercise of 350,000 ACI Canada legacy performance options at a price of \$0.01 per share for total proceeds of \$3,500.

In March 2022, the Company issued 45,511 Common shares for the exercise of 28,011 Common shares options at a price of CAD\$0.714 per share for total proceeds of \$25,570 (CAD\$32,495).

In April 2022, the Company appointed Don Kalkofen as new Chief Financial Officer ("CFO"), replacing Jeremy Wright.

In April 2022, the Company granted 450,000 share options to the new CFO of the Company with an exercise price of CAD\$0.93 per share for a period of ten years from date of grant. The options will be subject to the following vesting terms: 25% will vest in equal monthly instalments until April 11, 2023 and the remaining 75% will vest in equal monthly instalments until April 11, 2025.

In April 2022, Michael McFadden, the CEO of the Company, was appointed to the board of directors

In May 2022, the Company granted 90,000 share options with an exercise price of CAD\$0.64 per share. The options will be subject to the following vesting terms: 25% will vest on date of grant and the remaining 75% will vest in equal monthly instalments over a 24 month period.

## ARRANGEMENT AGREEMENT

On October 27, 2020, ACI Canada entered into an Arrangement Agreement with ACI whereby ACI would acquire 100% of the issued and outstanding shares of ACI Canada by issuing to the shareholders of ACI Canada one common share of ACI ("CPC Share") for every one common share of ACI Canada share held by each ACI Canada shareholder (the "Transaction"). Certain US resident ACI Canada shareholders agreed to receive a restricted voting share (a "Restricted Voting Share") in place of a CPC Share which is equivalent to a CPC Share except that it will not be counted in a shareholder vote for the election of directors. In addition, holders of Class C Preferred shares of ACI Canada received one Class B Preferred Share of ACI for each Class C Preferred share of ACI Canada held by such shareholder. The outstanding options and warrants of ACI Canada became convertible into options and warrants of ACI.

On March 18, 2021, the Transaction completed resulting in ACI acquiring 100% of the shares of ACI Canada and ACI Canada's shareholders receiving 42,615,495 post-consolidated common shares, 7,000,000 restricted voting shares, 7,916,380 preferred shares, 11,819,169 warrants, and 10,069,365 share options of ACI. The ACI shareholders retained 1,640,507 common shares on completion of the transaction and the former ACI share option holders were granted 108,543 share options.

The transaction constituted a reverse acquisition of ACI and has been accounted for as a reverse acquisition transaction in accordance with the guidance provided under IFRS 2, *Share-based Payment* and IFRS 3, *Business Combinations*. As ACI did not qualify as a business according to the definition in IFRS 3, *Business Combination*, this reverse acquisition does not constitute a business combination; rather the transaction was accounted for as an asset acquisition by the issuance of shares of the Company, for the net assets of ACI and its public listing. Accordingly, the transaction has been accounted for at the fair value of the equity instruments granted by the shareholders of ACI Canada to the shareholders and option holders of ACI. The sum of the fair value of the consideration paid (based on the fair value of the ACI shares just prior to the reverse acquisition) less the ACI net assets acquired, has been recognized as a listing expense in profit or loss for the year ended December 31, 2021.

For accounting purposes, ACI Canada was treated as the accounting parent company (legal subsidiary) and ACI has been treated as the accounting subsidiary (legal parent) in these condensed interim consolidated financial statements. As ACI Canada was deemed to be the acquirer for accounting purposes, its assets, liabilities and operations since incorporation are included in the consolidated financial statements at their historical carrying value. The results of operations of ACI are included in the consolidated financial statements from the date of the reverse acquisition of March 18, 2021.

## **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.

Critical judgments exercised in applying accounting policies that have the most significant effect on the amounts recognized in the consolidated financial statements are as follows:

#### Uncertainty of COVID-19 Global Pandemics

The Company is subject to risks and uncertainties as a result of the ongoing COVID-19 pandemic. The Company is continuing to closely monitor the impact of the COVID-19 pandemic on its business and has taken and continues to take proactive efforts to protect the health and safety of its patients, clinical research staff and employees, and to maintain business continuity. The extent of the impact of the COVID-19 pandemic on the Company's activities remains uncertain and difficult to predict, as the response to the pandemic is ongoing and information continues to evolve. Capital markets and economies worldwide have been negatively impacted by the COVID-19 pandemic and may be further impacted in the future. Such economic disruption could have a material adverse effect on the Company's business. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remains uncertain.

The severity of the impact of the COVID-19 pandemic on the Company's activities will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, including the severity of any additional periods of increases or spikes in the number of cases in the areas the Company its suppliers and its manufacturers operate and areas where the Company's clinical trial sites are located; the development and spread of COVID-19 variants, the timing, extent, effectiveness and durability of COVID-19 vaccine programs or other treatments; and new or continuing travel and other restrictions and public health measures, such as social distancing, business closures or disruptions, Accordingly, the extent and severity of the impact on the Company's existing and planned clinical trials, manufacturing, collaboration activities and operations is uncertain and cannot be fully predicted. The Company may experience delays in its existing and planned clinical trials due to the worldwide impacts of the pandemic. The Company's future results of operations and liquidity could be adversely impacted by delays in existing and planned clinical trials, continued difficulty in recruiting patients for these clinical trials, delays in manufacturing and collaboration activities, supply chain disruptions, the ongoing impact on its operating activities and employees, and the ongoing impact of any initiatives or programs that the Company may undertake to address financial and operational challenges. As of the date of issuance of these consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact the Company's future financial condition, liquidity or results of operations remains uncertain

# 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. As at June 30, 2022, the functional currency of the Company is CAD and its subsidiaries is the USD.

## 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, 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.

Information about assumptions and estimation uncertainties that have a risk of resulting in significant adjustments are as follows:

## 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 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.

# Useful lives of intangible assets

The Company records intangible assets acquired at their fair value. Determining fair value requires management to use estimates that could be material. Following initial recognition, the Company carries the value of intangible assets at cost less accumulated amortization and any accumulated impairment losses. 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.

## **SELECTED QUARTERLY INFORMATION**

The following financial data is derived from the Company's unaudited condensed interim consolidated financial statements for the three and six months ended June 30, 2022 and 2021.

	Three months ended		Six months ended	
	June	30,	June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Operating expenses	(4,417,993)	(2,267,844)	(7,360,315)	(4,723,909)
Other income (expenses)	1,414,160	2,386,517	1,443,158	(7,382,366)
Net (loss) income	(3,003,833)	118,673	(5,917,157)	(12,106,275)
Currency translation adjustment	(376,526)	5,712	(176,449)	5,712
Comprehensive (loss) income	(3,380,359)	124,385	(6,093,606)	(12,100,563)
Basic and diluted loss per common share	(0.05)	(0.00)	(0.09)	(0.25)
Working capital (deficiency)				
Total assets	6,840,674	6,439,269	6,840,674	6,439,269
Total long-term liabilities	675,983	6,550,718	675,983	6,550,718

## **RESULTS OF OPERATIONS – Three Months Ended June 30, 2022**

During the three months ended June 30, 2022, the Company's primary focus was on the continued development of ALPHA-1062 and ALPHA-602.

For the three months ended June 30, 2022, operating expenses increased by \$2,150,149 from \$2,267,844 in the three months ended June 30, 2021 to \$4,417,993 in the three months ended June 30, 2022 primarily as a result of:

Operating Expense	Increase / Decrease in Expenses	Explanation for Change
Management fees and salaries	Increase of \$124,041	Increased in part due to the hiring of a new CFO in 2022 Q2.
Professional fees	Increase of \$120,591	Increased primarily due to additional legal and accounting fees relating to increased corporate activity.
Research and development	Increase of \$1,445,138	Increased due to increased activity into the development of ALPHA-1062 and ALPHA-0602.
Share-based compensation	Increase of \$333,681	Increased due to additional share options with graded vesting being granted during 2021 year end and the first half of 2022.

The following occurred during the three months ended June 30, 2022 as compared to the three months ended June 30, 2021:

• The Company recorded a decrease in the gain on derivative liability of \$1,096,417 on the revaluation of the derivative liability relating to the warrants with an exercise price in USD.

## **RESULTS OF OPERATIONS - Six Months Ended June 30, 2022**

During the six months ended June 30, 2022, the Company's primary focus was on the continued development of ALPHA-1062 and ALPHA-602.

For the six months ended June 30, 2022, operating expenses increased by \$2,636,406 from \$4,723,909 in the six months ended June 30, 2021 to \$7,360,315 in the six months ended June 30, 2022 primarily as a result of:

Operating Expense	Increase / Decrease in Expenses	Explanation for Change
Accretion expenses	Decrease of \$368,154	Decreased due to conversion of convertible promissory notes in 2021 Q1.
Management fees and salaries	Increase of \$265,443	Increased due to the hiring of a new management team starting with the addition of the new CEO in 2021 Q2.
Professional fees	Increase of \$193,092	Increased due to additional legal and accounting fees relating to increased corporate activity.
Research and development	Increase of \$1,598,611	Increased due to increased activity into the development of ALPHA-1062 and ALPHA-0602.
Share-based compensation	Increase of \$537,003	Increased due to additional share options with graded vesting being granted during 2021year end and the first half of 2022.

The following occurred during the six months ended June 30, 2022 as compared to the six months ended June 30, 2021:

• The Company recorded a gain on derivative liability of \$1,353,450 on the revaluation of the derivative liability relating to the warrants with an exercise price in USD.

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

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

	Q2 F2022	Q1 F2022	Q4 F2021	Q3 F2021
	\$	\$	\$	\$
Operating expenses	(4,417,993)	(2,942,322)	(4,253,019)	(3,119,960)
Other income (expenses)	1,414,160	28,998	1,103,331	(1,169,093)
Income (loss) for the period	(3,003,833)	(2,913,324)	(3,149,688)	(4,289,053)
Currency translation adjustment	(376,526)	200,007	(46,738)	(60,508)
Comprehensive income (loss) for the period	(3,380,359)	(2,713,247)	(3,221,255)	(4,349,561)
Loss per share	(0.05)	(0.04)	(0.05)	(0.08)
Weighted average shares	68,023,450	67,815,580	65,016,609	51,843,927

	Q2	Q1	Q4	Q3
	F2021	F2021	F2020	F2020
	\$	\$	\$	\$
Operating expenses	(2,267,844)	(2,456,065)	(2,134,928)	(1,537,044)
Other income (expenses)	2,386,517	(9,768,883)	487,129	90,850
Income (loss) for the period	118,673	(12,224,948)	(1,647,799)	(1,446,194)
Currency translation adjustment	5,712	-	-	
Comprehensive income (loss) for the period	124,385	(12,224,948)	(1,647,199)	(1,446,194)
Loss per share	(0.00)	(0.28)	(0.04)	(0.03)
Weighted average shares	51,843,927	44,372,787	42,996,524	42,998,154

The variations in net loss from quarter to quarter are a result of the extent of the amount of administrative expenses needed, 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:

- the quarter ended June 30, 2022 included a gain on the revaluation of the derivative liability of \$1,266,779
- the quarter ended September 30, 2021 included a loss on the revaluation of derivative liability of \$1,179,404;
- the guarter ended June 30, 2021 included a gain on the revaluation of derivative liability of \$2,363,196;
- the quarter ended March 31, 2021 included share-based compensation in research and development of \$498,351, listing expense of \$1,404,200 from the arrangement agreement, and the recognition of the derivative liability of \$7,810,547 for the warrants with an exercise price in USD; and
- the quarter ended December 31, 2020 included an accretion expense \$390,453 for the conversion of the convertible debentures and professional fees of \$188,373 relating to the assistance with the arrangement agreement.

# LIQUIDITY AND CAPITAL RESOURCES

The Company has not generated revenues from its operations to date and as at June 30, 2022, had a deficit of \$43,951,060 (December 31, 2021 - \$38,033,903) which has been primarily financed by equity. The Company had \$5,975,457 in Cash and \$2,001,397 in current liabilities as of June 30, 2022. The Company's continuing operations, as intended, are highly dependent upon its ability to generate cash flows or obtain additional financing. Management is of the opinion that it does not have sufficient working capital to meet the Company's liabilities and commitments as they become due for the upcoming 12 months and as planned.

Management recognizes it will need to raise addition financing to cover development and operating costs over coming months. 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

The Company initiated cost cutting measures to extend cash runway and reduce quarterly cash burn. The Company streamlined R&D programs and will focus on ALPHA-1062 and reduced headcount and other operating costs not essential to the ALPHA-1062 NDA file.

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:

	Six months ended June 30,	
	2022	2021
	\$	\$
Cash flows used in operating activities	(5,155,102)	(3,023,439)
Cash flows (used in ) provided by investing activities	(4,876)	437,653
Cash flows provided by financing activities	28,785	1,913,032
Effect of foreign exchange on cash	(195,143)	-
Decrease in cash during the year	(5,326,336)	(672,754)
Cash, beginning of period	11,301,793	5,926,350
Cash, end of period	5,975,457	5,253,596

The cash flow used in operating activities increased by \$2,131,663 to \$5,155,102 for the six months ended June 30, 2022 from \$3,023,439 for the comparative period. The increase in cash flow from operating activities represents the effect on cash flows from net losses adjusted for items not affecting cash, principally: accrued interest expenses, 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 (used in) investing activities for the six months ended decreased by \$442,529 compared to the comparative period due to minimal investing activities being incurred during the six months ended June 30, 2022

Cash provided by financing activities for the six months ended June 30, 2022 decreased by \$1,884,247 compared to the comparative period. During the six months ended June 30, 2021, financing activities included raising \$2,267,899 from the issuance of common shares and net of share issuance costs of \$351,784.

## **OFF BALANCE SHEET ARRANGEMENTS**

The Company did not have any off-balance sheet arrangements as at June 30, 2022 or the date of this report.

## COMMITMENTS

## 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;
  - o 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 (Note 7).

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.

## 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.

## **CONTINGENCIES**

The Company did not have any contingencies as at June 30, 2022 or the date of this report.

## TRANSACTIONS WITH RELATED PARTIES

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 requires 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.

In September 2018, the Company signed a management agreement with 9177 – 586 Quebec Inc. ("9177 Quebec"), a company controlled by Denis Kay, the Chief Scientific Officer of the Company, which requires 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.

In September 2018, the Company signed a management agreement with Clearway Global, LLC ("Clearway Global"), a company controlled by Fred Sancilio, the former President and a director of the Company, which requires monthly payments of \$10,000 per month for an effective term of two years. In June 2019, the Company amended the agreement to increase the monthly fees to \$20,000. Included in the agreement is a provision for a termination payment equal to the greater of (i) \$480,000 less any fees previously paid under the agreement between June 1, 2019 and the date of termination or (ii) \$60,000. In February 2021, the Company amended the agreement to increase the monthly fees to \$24,166. On December 22, 2021, Fred Sancilio resigned as the President and director of the Company. The management agreement was replaced with a consulting agreement with no longer a provision for a termination payment.

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 requires 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 tweleve 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 terminate 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 tweleve 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 entitling him to a cash bonus equal to an amount by which the fair market value of one common share of the Company, calculated as the 30-day Volume Weighted Average Price ("VWAP") per common share, exceeds \$1.58 times the number of bonus rights vested. The bonus rights earned will vest on the earlier of the date of a change of control or April 15, 2024 and will be payable upon vesting. The bonus rights will be earned based on the price of the Company's common share exceeding certain thresholds. As at June 30, 2022, Mr. McFadden had earned 1,639,148 bonus rights.

In May 2021, the Company hired Lauren D'Angelo, the Chief Commercial Officer of the Company, requiring an annual base compensation of \$350,000. Included in the agreement is a provision for termination payment due to a change of control, the COO 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 May 2022, Ms. D'Angelo was granted the ability to earn up to 1,065,446 bonus rights entitling her to a cash bonus equal to an amount by which the fair market value of one common share of the Company, calculated as the 30-day VWAP per common share, exceeds \$1.58 times the number of bonus rights vested. The bonus rights earned will vest on the earlier of the date of a change of control or April 15, 2024 and will be payable upon vesting. The bonus rights will be earned based on the price of the Company's common share exceeding certain thresholds. As at June 30, 2022, Ms. D'Angelo had earned 737,616 bonus rights.

In November 2021, the Company signed an employment agreement with Cedric O'Gorman, the Chief Medical Officer 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 an amount equal to annual base compensation for a period of three 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.

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, the CFO 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.

During the six months ended June 30, 2022, the Company entered into the following transactions with related parties:

- a) Incurred management fees of \$108,413 (June 30, 2021 \$108,000) and share-based compensation of \$nil (June 30, 2021 \$112,768) to CMI. During the six months ended June 30, 2021, CMI converted the First Note debenture into 21,712 shares of the Company for the principal and interest portion. CMI also converted its Second Note debenture into 16,625 units of the Company with each unit consisting of one common share and one-half warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023. As at June 30, 2022, \$19,072 (December 31, 2021 \$19,064) was included in accounts payable and accrued liabilities owing to CMI.
- b) Incurred management fees of \$140,409 (June 30, 2021 \$91,898) to Seatrend. As at June 30, 2022, \$72 (December 31, 2021 \$73) was included in accounts payable and accrued liabilities owing to Seatrend.
- c) Incurred management fees included in research and development of \$90,000 (June 30, 2021 \$90,000) and share-based compensation included in research and development of \$11,035 (June 30, 2021 \$112,768) to 9177 Quebec. During the six months ended June 30, 2021, 9177 Quebec converted its First Note debenture into 10,856 shares of the Company for the principal and interest portion. 9177 Quebec also converted its Second Note debenture into 8,312 units of the Company with each unit consisting of one common share and one-half warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023. As at June 30, 2022, \$17,250 (December 31, 2021 \$27,450) was included in accounts payable and accrued liabilities owing to 9177 Quebec.
- d) Incurred management fees included in research and development of \$nil (June 30, 2021 \$200,833) and share-based compensation included in research and development of \$nil (June 30, 2021 \$417,395) to Clearway Global. During the six months ended June 30, 2021, Clearway Global converted its First Note debenture into 21,712 shares of the Company for the principal and interest portion. Clearway Global also converted its Second Note debenture into 16,625 units of the Company with each unit consisting of one common share and one-half warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023.
- e) As of June 30, 2022, \$nil (December 31, 2021 \$2,000) was included in accounts payable and accrued liabilities owing to Olera LLC, a company controlled by Fred Sancilio.

- f) Incurred share-based compensation of \$91,431 (June 30, 2021 \$nil) to Len Mertz, a director of the Company. During the six months ended June 30, 2021, Mr. Mertz, Mertz Holdings and Mertz Trust, entities controlled by Len Mertz, converted their First Note debentures into 562,518 shares of the Company for the principal and interest portion. Additionally, their Second Note debentures were converted into 430,428 units of the Company with each unit consisting of one common share and one share purchase warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023.
- g) Incurred share-based compensation of \$78,248 (June 30, 2021 \$nil) to John Havens, a director of the Company. During the six months ended June 30, 2021, Mr. Havens converted his First Note debenture into 492,392 shares of the Company for the principal and interest portion. Additionally, Mr. Havens converted his Second Note debenture into 376,838 units of the Company with each unit consisting of one common share and one share purchase warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023.
- h) Incurred share-based compensation of \$69,459 (June 30, 2021 \$nil) to Philip Mertz, a director of the Company. During the six months ended June 30, 2021, Mr. Mertz converted his First Note debenture into 164,365 shares of the Company for the principal and interest portion. Additionally, Mr. Mertz converted his Second Note debenture into 125,854 units of the Company with each unit consisting of one common share and one share purchase warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023.
- i) Incurred share-based compensation of \$69,459 (June 30, 2021 \$nil) to Rob Bakshi, a director of the Company. During the six months ended June 30, 2021, Vincorp Holdings, a company controlled by Mr. Bakshi, converted its First Note debenture into 10,856 shares of the Company for the principal and interest portion. Additionally, Vicorp Holdings converted its Second Note debenture into 8,312 units of the Company with each unit consisting of one common share and one share purchase warrant with each warrant entitling the holder to acquire one common share of the Company for CAD\$2.10 up to March 18, 2023.
- j) During the six months ended June 30, 2022, the Company paid \$nil (June 30, 2021 \$3,642) in legal fees and \$7,153 (June 30, 2021 \$18,000) in administrative fees, included in other general and administrative expenses, to Cawkell Brodie LLP, a law firm where Mr. Cawkell is a managing partner. As of June 30, 2022, \$1,260 (December 31, 2021 \$nil) was included in accounts payable and accrued liabilities owing to Cawkell Brodie LLP.
- k) Incurred management fees and salaries of \$250,000 (June 30, 2021 \$137,820) and share-based compensation of \$375,241 (June 30, 2021 \$nil) to Michael McFadden. As at June 30, 2022, \$6,848 (December 31, 2021 \$nil) was included in accounts payable and accrued liabilities to Mr. McFadden.
- Incurred management salaries included in research in development of \$179,415 (June 30, 2021 \$nil) and share-based compensation included in research and development of \$138,037 (June 30, 2021 \$nil) to Lauren D'Angelo, the Company's Chief Commercial Officer. As at June 30, 2022, \$1,534 (December 31, 2021 \$64,320) was included in accounts payable and accrued liabilities owing to Ms. D'Angelo.
- m) Incurred management salaries included in research and development of \$200,000 (June 30, 2021 \$nil) and share-based compensation included in research and development of \$88,174 (June 30, 2021) to Cedric O'Gorman, the Company's Chief Medical Officer. As at June 30, 2022, \$1,791 (December 31, 2021 \$16,667) was included in accounts payable and accrued liabilities owing to Mr. O'Gorman.
- n) Incurred management fees and salaries of \$95,455 (June 30, 2021 \$nil) and share-based compensation of \$48,094 (June 30, 2021 \$nil) to Don Kalkofen. As at June 30, 2022, \$993 (December 31, 2021 \$nil) was included in accounts payable and accrued liabilities to Mr. Kalkofen.

Summary of key management personnel compensation:

	For the six months ended June 30,		
	2022 2021		
	\$	\$	
Other general and administrative	7,153	18,000	
Management fees and salaries	594,277	337,718	
Professional fees	-	3,642	
Research and development - management fees and salaries	469,415	347,928	
Share-based compensation	969,178	642,931	
	2,040,023	1,350,219	

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, other current assets, accounts payable, derivative liability, and promissory note. The fair values of subscription receipts receivable, other current assets, accounts payable, related parties payable, refundable subscription receipts, convertible debentures and promissory note approximates their carrying values either due to their current nature or current market rates for similar instruments. Cash is measured at fair value on a recurring basis using level 1 inputs. Derivative liability is 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 derivative liability are described in Note 8 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 June 30, 2022, the Company had net monetary assets of approximately \$6,800,000 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 \$530,000. 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. 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, other receivables, and tax recoverable at June 30, 2022 and December 31, 2021.

## 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 June 30, 2022, the promissory note bears interest of 2% 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 June 30, 2022, the Company had a cash balance of \$5,975,457 to settle current financial liabilities of \$2,001,397.

Contractual undiscounted cash flow requirements for financial liabilities as at June 30, 2022 are as follows:

	≤1 Year	>1-3 Years	Total
	\$	\$	\$
Accounts payable	694,210	-	694,210
Promissory note	1,211,463	=	1,211,463
	1,905,673	-	1,905,673

# OTHER RISKS AND UNCERTAINTIES

The business and operations of the Company are subject to numerous risks, 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.

#### **Global Pandemics**

The Company is subject to risks and uncertainties as a result of the ongoing COVID-19 pandemic. The Company is continuing to closely monitor the impact of the COVID-19 pandemic on its business and has taken and continues to take proactive efforts to protect the health and safety of its patients, clinical research staff and employees, and to maintain business continuity. The extent of the impact of the COVID-19 pandemic on the Company's activities remains uncertain and difficult to predict, as the response to the pandemic is ongoing and information continues to evolve. Capital markets and economies worldwide have been negatively impacted by the COVID-19 pandemic and may be further impacted in the future. Such economic disruption could have a material adverse effect on the Company's business. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remains uncertain.

The severity of the impact of the COVID-19 pandemic on the Company's activities will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, including the severity of any additional periods of increases or spikes in the number of cases in the areas the Company its suppliers and its manufacturers operate and areas where the Company's clinical trial sites are located; the development and spread of COVID-19 variants, the timing, extent, effectiveness and durability of COVID-19 vaccine programs or other treatments; and new or continuing travel and other restrictions and public health measures, such as social distancing, business closures or disruptions. Accordingly, the extent and severity of the impact on the Company's existing and planned clinical trials, manufacturing, collaboration activities and operations is uncertain and cannot be fully predicted. The Company may experience delays in its existing and planned clinical trials due to the worldwide impacts of the pandemic. The Company's future results of operations and liquidity could be adversely impacted by delays in existing and planned clinical trials, continued difficulty in recruiting patients for these clinical trials, delays in manufacturing and collaboration activities, supply chain disruptions, the ongoing impact on its operating activities and employees, and the ongoing impact of any initiatives or programs that the Company may undertake to address financial and operational challenges. As of the date of issuance of these consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact the Company's future financial condition, liquidity or results of operations remains uncertain.

## **Financing Risks**

We have limited capital and we expect we will require funds in excess of our existing cash resources to fund operating deficits, develop existing and new products or services, establish and expand our marketing capabilities, and finance general and administrative activities. We do not currently generate sufficient cash from our businesses to fund our operations. We do not have any bank credit facility or other working capital credit line under which we may borrow funds for working capital or other general corporate purposes. If we do not have, or are not able to obtain, sufficient funds, we expect to have to delay strategic opportunities, investments, or projects. If we are unable to raise adequate funds, we may have to delay or reduce the scope of, or eliminate some or all of our current research and development. Any of these actions could have a material adverse effect on our business, results of operations or financial condition.

## 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 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.

#### **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 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.

## **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.

## **Retention of Skilled Management**

Our success depends to a significant extent on our ability to identify, hire, and retain qualified creative, technical and managerial personnel in a competitive job market. We expect competition for personnel with the specialized creative and technical skills needed to create our products and provide our services will continue to intensify in future. Our competitors may be able to offer a work environment with higher compensation or more opportunities to work with cutting-edge technology than we can. If we are unable to retain our key personnel or appropriately match skill sets with our needs, we would be required to expend significant time and financial resources to identify and hire new qualified personnel and to transfer significant internal historical knowledge, which might significantly delay or prevent the achievement of our business objectives.

## **Intellectual Property**

Patents issued or licensed to the Company and trademarks registered or licensed to the Company may be infringed upon by the products or processes of others. We hold a number of trademarks and copyrights relating to certain significant products. We rely on patent laws and contractual provisions to protect these patents, and

there can be no assurance that third parties will not infringe or misappropriate our patents. The monitoring and enforcement against the unauthorized use of our intellectual property rights could entail significant expenses and could prove difficult or impossible. As well, the laws of other countries in which we may choose to market our products may afford little or no effective protection of our intellectual property. If we lose some or all of our intellectual property rights, our business may be materially adversely affected.

## **Dilution to Current Shareholders**

In order to finance our operations, we have raised funds through the issuance of common shares and securities convertible into common shares and expect to do so again in future. We cannot predict the size of future issuances of common shares or the size or terms of future issuances of debt instruments or other securities convertible into common shares, or the effect, if any, that future issuances and sales of our securities will have on the market price of our common shares. Sales or issuances of substantial numbers of common shares, or the perception that such sales could occur, may adversely affect the market price of our common shares. With any additional sale or issuance of common shares, or securities convertible into common shares, our investors will suffer dilution to their voting power.

#### ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

A number of amendments to standards and interpretations applicable to the Company are not yet effective for the six months ended June 30, 2022 and have not been applied in preparing the Interim Financial Statements nor does the Company expect these amendments to have a significant effect on its Interim Financial Statements.

# 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 six months ended June 30, 2022.

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 share")
- Unlimited Class A restricted voting shares without par value ("Restricted share")
- Unlimited Class B preferred Series A shares without par value ("Class B preferred shares")

Below is a summary of the common shares issued, stock options, and share purchase warrants as at June 30, 2022 and the date of this report:

	June 30, 2022	Date of this Report	
Common shares	61,023,450	61,023,450	
Restricted shares	7,000,000	7,000,000	
Class B preferred shares	7,916,380	7,916,380	
Common share options	6,401,071	6,121,071	
ACI Canada legacy performance options	9,591,057	9,591,057	
Warrants	15,981,290	15,981,290	

# **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 share options are outstanding and exercisable:

Options Outstanding	Options Exercisable	Exercise Price	Expiry Date
200,000	200,000	1.63 (CAD\$2.10)	March 29, 2023
31,513	31,513	0.55 (CAD\$0.714)	September 21, 2023
39,154	39,154	0.40	June 1, 2029
39,154	39,154	0.40	July 22, 2030
2,700,000	-	0.70 (CAD\$0.90)	August 3, 2031
400,000	225,000	1.22	August 16, 2031
131,250	131,250	0.80	August 16, 2031
1,440,000	746,250	0.87 (CAD\$1.12)	December 20, 2031
230,000	-	0.81 (CAD\$1.05)	February 14, 2032
450,000	37,500	0.72 (CAD \$0.93)	April 11, 2032
460,000	225,000	0.50 (CAD\$0.64)	May 31, 2032
6,121,071	1,674,821		

## **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:

Options Outstanding	Options Exercisable	Exercise Price	Expiry Date
		\$	
900,000	900,000	0.001	February 1, 2026
691,057	691,057	0.01	December 31, 2027
4,250,000	3,960,000	0.01	September 1, 2028
3,750,000	3,180,000	0.01	June 1, 2029
9,591,057	8,731,057		

# **Warrants**

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

Warrants	Formation Button	Familia Data
Outstanding	Exercise Price	Expiry Date
	\$	
40,000	0.40	July 5, 2023
3,061,783	0.40	August 30, 2024
2,486,647	1.68 (CAD\$2.10)	March 18, 2023
130,733	1.28 (CAD\$1.60)	March 18, 2023
9,602,500	1.40 (CAD\$1.75)	October 1, 2023
659,627	1.20 (CAD\$1.50)	October 1, 2023
15,981,290		

## **OTHER MD&A REQUIREMENTS**

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

- SEDAR at www.sedar.com;
- the Company's audited consolidated financial statements for the years ended December 31, 2021 and 2020; and
- the Company's unaudited condensed interim financial statements for the three and six months ended June 30, 2022.

This MD&A was approved by the Board of Directors of Alpha Cognition Inc. effective August 25, 2022.