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**Annual Information Form**

For the year ended December 31, 2022

Dated as of June 26, 2023

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## PRELIMINARY NOTES

### Date of Information

Unless otherwise indicated, all information contained in this Annual Information Form (“AIF”) of Alpha Cognition Inc. (“Alpha” or the “Company”) is as of December 31, 2022.

### Documents Incorporated by Reference

Incorporated by reference into this AIF are the following documents:

- Filing Statement in respect of the Qualifying Transaction of Crystal Bridge Enterprises Inc. dated as of March 16, 2021 (the “Filing Statement”).
- Audited consolidated financial statements of the Company for the years ended December 31, 2022 and 2021, together with the notes thereto and the report of independent auditors therein.
- Management’s discussion and analysis of the Company for the year ended December 31, 2022 (the “Annual MD&A”).

Copies of documents incorporated by reference are available under the Company’s profile on the SEDAR website at [www.sedar.com](http://www.sedar.com).

Any statement contained in a document incorporated or deemed to be incorporated by reference herein will be deemed to be modified or superseded for the purposes of this AIF to the extent that a statement contained in this AIF or in any subsequently filed document that also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded will not constitute a part of this AIF, except as so modified or superseded. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of such a modifying or superseding statement will not be deemed an admission for any purpose that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made.

### Forward-looking Information

Certain statements contained in this AIF, and in certain documents incorporated by reference herein, contains statements that, to the extent that they are not historical fact, may constitute “forward-looking statements” within the meaning of applicable securities legislation.

Forward-looking statements may include, but are not limited to, statements with respect to:

- financial and other projections, future plans, objectives, performance, revenues, growth, profits or operating expense;
- the use of available funds;
- plans to research, develop, implement, adopt, market and sell new technology or products, including continued research, development and commercialization regarding the Company’s products and proposed products;

- estimates and projections regarding the industry in which the Company operates or will operate, including the global pharmaceutical and biotechnology markets, and expectations relating to trends and the adoption of new products;
- requirements for additional capital and future financing options;
- plans to launch new products and identify qualified distribution partners;
- expansion and acceptance of the Company's products in different markets;
- manufacturing, license and distribution partnerships and agreements;
- plans to identify, pursue, negotiate and/or complete strategic acquisitions;
- marketing plans;
- hiring and retaining employees and management necessary to execute on company objectives;
- the timing and possible outcome of regulatory and legislative matters, including, without limitation, planned NDA filings with the FDA, planned FDA, EU and other regulatory approval processes;
- future plans, objectives or economic performance, or the assumption underlying any of the foregoing;
- planned out-licencing of any assets; and
- other expectations of the Company.

Often, but not always, forward-looking statements can be identified by the use of words such as “plans”, “expects”, “is expected”, “budget”, “scheduled”, “project”, “estimates”, “forecasts”, “intends”, “anticipates”, or “believes” or variations (including negative variations) of such words and phrases, or statements that certain actions, events or results “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved.

Such forward-looking statements, made as of the date hereof, reflect the Company's current views with respect to future events and are based on information currently available to the Company and are subject to and involve certain known and unknown risks, uncertainties, assumptions and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed in or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results may vary materially from those described herein as intended, planned, anticipated, believed, estimated or expected. These risks, uncertainties, assumptions and other factors should be considered carefully, and prospective investors and readers should not place undue reliance on the forward-looking statements.

These risks, uncertainties, assumptions and other factors include, but are not limited to: the risks and factors set out in this AIF, including as set out in Schedule “B - Risk Factors” attached hereto; risks posed by the economic and political environments in which the Company operates and intends to operate; rising global inflation; the potential for losses arising from the expansion of operations into new markets; increased competition; assumptions regarding market trends and the expected demand and desires for the Company's products and proposed products; reliance on industry manufacturers, suppliers and others; the failure to adequately protect intellectual property; failure to comply with regulatory requirements; clinical trial results may not be adequate to meeting FDA filing requirements and may require continued clinical efforts; a failure to adequately manage future growth; failure to raise sufficient capital to continually fund operations; failure to hire and retain executive and employee resources; adverse market conditions; and failure to satisfy ongoing regulatory requirements.

Any forward-looking statement speaks only as of the date on which such statement is made, and the Company undertakes no obligation to update any forward-looking statement or information or statements to reflect information, events, results, circumstances or otherwise after the date on which such statement is made or to reflect the occurrence of unanticipated events, except as required by law including securities

laws. New factors emerge from time to time, and it is not possible for management to predict all of such factors and to assess in advance the impact of each such fact on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements or information.

### Currency

All dollar amounts in this AIF are expressed in Canadian dollars unless otherwise indicated.

## GLOSSARY OF TERMS

In this AIF, the following terms have the meanings set forth herein:

“**ACA**” means the United States *Patient Protection and Affordable Care Act*, as amended by the *Health Care and Education Reconciliation Act of 2010*;

“**AChEI**” means acetylcholine esterase inhibitor;

“**AIF**” means this annual information form of the Company for the year ended December 31, 2022;

“**Alpha**” or the “**Company**” means Alpha Cognition Inc. (formerly Crystal Bridge Enterprises Inc.);

“**ALPHA-0602**” is a specific form of progranulin, a natural protein that is expressed in several cell types in the central nervous system and in peripheral tissues, and which is being developed by the Company as a treatment for ALS. See “*Information Concerning the Target Company – Summary of the Business – ALPHA-0602*” in the Filing Statement;

“**ALPHA-0702 and ALPHA-0802**” are 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.

“**ALPHA-1062**” is a patented new active ingredient that is being developed by the Company as a treatment for Alzheimer's Disease. See “*Information Concerning the Target Company – Summary of the Business – ALPHA-1062*” in the Filing Statement;

“**ALPHA-1062IN**” is a patented new chemical entity being developed as a next generation acetylcholinesterase inhibitor that is also being developed for the treatment of TBI. ALPHA-1062IN'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, attention, and stimulation of cholinergic pathway.

“**Alpha Canada**” or “**Target Company**” means Alpha Cognition Canada Inc. (formerly Alpha Cognition Inc.);

“**ALS**” means amyotrophic lateral sclerosis, a group of rare, progressive, neurological diseases that mainly involve the nerve cells (neurons) responsible for controlling voluntary muscle movement;

“**Alzheimer's Disease**” is a chronic neurodegenerative disease that destroys brain cells, causing cognitive functions, including thinking ability and memory, to deteriorate over time;

- “**ANDA**” means an abbreviated new drug application;
- “**AKS**” means the United States Federal Anti-Kickback Statute;
- “**Audit Committee**” means the Company’s audit committee of the Board;
- “**BCBCA**” means the *Business Corporations Act* (British Columbia), as amended and supplemented from time to time;
- “**BLA**” means Biologics License Application;
- “**Board**” means the board of directors of the Company;
- “**CCPA**” means the *California Consumer Privacy Act of 2018*;
- “**Centurion**” means Centurion Minerals Ltd.;
- “**CEO**” means the Chief Executive Officer;
- “**CFO**” means the Chief Financial Officer;
- “**cGMP**” means current good manufacturing practice requirements;
- “**CMS**” means Centers for Medicare & Medicaid Services;
- “**Common Shares**” means the common shares without par value in the capital of the Company;
- “**Compensation Committee**” means the Company’s compensation committee of the Board;
- “**Computershare**” means Computershare Investor Services Inc.;
- “**Consulting Agreement**” means the consulting agreement between the Company and Spartan;
- “**CPC Escrow Agreement**” means the escrow agreement dated August 30, 2018, between the Company, Computershare and certain shareholders of the Company;
- “**CPRA**” means the *California Privacy Rights Act*;
- “**CSE**” means the Canadian Securities Exchange;
- “**CTO**” means cease trade order;
- “**Deemed Issue Price**” has the meaning set out under “*Capital Structure – Preferred Shares*” of this AIF;
- “**Domestic Issuer**” means a “domestic issuer” as determined in accordance with the United States Securities Exchange Act of 1934;
- “**Escrow Agreement**” means the escrow agreement dated March 18, 2021, between the Company, Computershare and certain escrow shareholders;
- “**FDA**” means the United States Food and Drug Administration;

“**FDCA**” means the United States *Federal Food, Drug, and Cosmetic Act*;

“**Filing Statement**” means the filing statement in respect of the Qualifying Transaction of Crystal Bridge Enterprises Inc. dated as of March 16, 2021;

“**Foreign Private Issuer**” means a “foreign private issuer” as determined in accordance with the United States Securities Exchange Act of 1934;

“**GEMs**” has the meaning set out under “*Description of the Business – General – ALPHA-0602*” of this AIF;

“**GCP**” means Good Clinical Practice requirements;

“**Governance Committee**” means the Company’s governance and nomination committee of the Board;

“**IBA**” means the investment banking agreement between the Company and Spartan;

“**IND**” means Investigational New Drug Application;

“**Liquidation Preference**” has the meaning set out under “*Capital Structure – Preferred Shares*” of this AIF;

“**Listed Warrants**” means the warrants to purchase Common Shares of the Company that are listed for trading under the stock symbol “ACOG.WT”;

“**MAD Study**” has the meaning set out under “*Description of the Business – General – ALPHA-1062 Clinical Development*” of this AIF;

“**mTBI**” means mild-traumatic brain injury;

“**NCE**” has the meaning set out under “*Description of the Business – General – Market Exclusivity*” of this AIF;

“**NDA**” means New Drug Application;

“**Neurodyn**” means Neurodyn Life Sciences Inc.;

“**NI 52-110**” means National Instrument 52-110 *Audit Committees*;

“**NOLs**” means net operating losses;

“**OIG**” means the United States Federal Office of Inspector General;

“**PDUFA**” means the United States *Prescription Drug User Fee Act*;

“**PGRN**” means progranulin;

“**PREA**” means the United States *Pediatric Research Equity Act of 2003*;

“**Preferred Shares**” means the Series A, Class B preferred voting shares, with special rights and restrictions, in the capital of the Company;

“**Qualifying Transaction**” means the qualifying transaction of Crystal Bridge Enterprises Inc. that was completed on March 18, 2021;

“**REMS**” means risk evaluation and mitigation strategies;

“**Restricted Shares**” means the Class A restricted voting shares, with special rights and restrictions, in the capital of the Company;

“**SAD Study**” has the meaning set out under “*Description of the Business – General – ALPHA-1062 Clinical Development*” of this AIF;

“**SEC**” means the U.S. Securities and Exchange Commission;

“**SEDAR**” means the System for Electronic Document Analysis and Retrieval;

“**Seed Share Resale Restrictions**” has the meaning set out under “*Escrowed Securities and Securities Subject to Contractual Restrictions on Transfer*” of this AIF;

“**Spartan**” means Spartan Capital Securities, LLC;

“**Tax Act**” means the United States Federal Income Tax Act;

“**TBI**” means traumatic brain injury;

“**TDP-43**” means the DNA binding protein 43 kDa;

“**TSX-V**” means the TSX Venture Exchange;

“**U.S. Exchange Act**” means the United States Securities Exchange Act of 1934; and

“**Warrant**” means a warrant to acquire one Common Share.

## **CORPORATE STRUCTURE**

### **Name, Address and Incorporation**

The Company was incorporated on November 15, 2017, under the *Business Corporations Act* (British Columbia) (“**BCBCA**”) under the name “Crystal Bridge Enterprises Inc.”. The Company is a reporting issuer in all of the provinces and territories of Canada, and its Common Shares are listed for trading on the CSE under the symbol “ACOG” and quoted on the OTCQB under the symbol “ACOGF”.

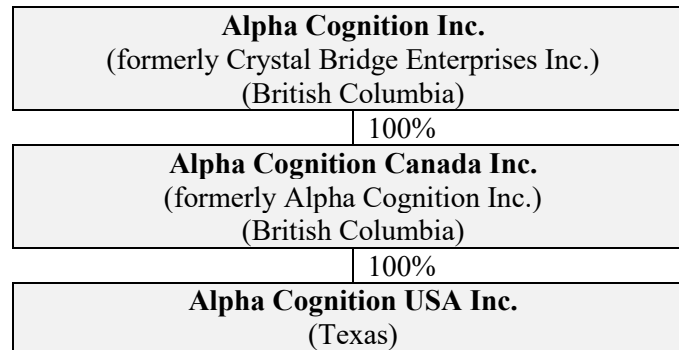
The Company completed its Qualifying Transaction with Alpha Cognition Canada Inc. (formerly Alpha Cognition Inc.) (“**Alpha Canada**”) on March 18, 2021, and changed its name to Alpha Cognition Inc. As a result of the Qualifying Transaction Alpha Canada became the Company’s wholly-owned subsidiary.

Alpha Canada was a privately held company incorporated pursuant to the BCBCA on May 16, 2014, under the name “Neurodyn Cognition Inc.”. On March 16, 2020, Alpha Canada changed its name to “Alpha Cognition Inc.” and on March 17, 2021, changed its name to “Alpha Cognition Canada Inc.”.



Alpha Canada has one wholly-owned subsidiary, Alpha Cognition USA Inc., which was incorporated pursuant to the laws of the State of Florida on August 19, 2019 and redomiciled to the State of Texas effective as of March 8, 2022.

The chart below sets out the intercorporate relationship between the Company, Alpha Canada and Alpha Cognition USA Inc.



The principal office of the Company is located at 301 – 1228 Hamilton Street, Vancouver, BC, V6B 6L2. The Company’s registered and records office is located at 1200 – 750 West Pender Street, Vancouver, BC, V6C 2T8. The Company’s phone number is 1-858-344-4375. The Company’s website is [www.alphacognition.com](http://www.alphacognition.com). Information contained on the Company’s website is not incorporated into this AIF.

## GENERAL DEVELOPMENT OF THE BUSINESS

### Three Year History

The principal business of the Company is focused on research and development in the field of neurodegeneration, with respect to a therapy for Alzheimer’s (ALPHA-1062) and subsequently with respect to a potential therapy for ALS (ALPHA-0602). For a discussion of the clinical and regulatory development of the technologies, please see the sections under the heading “*Description of the Business*” in this AIF.

Below is a description of the relevant history of the Company over the last three completed financial years:

On January 1, 2020, Alpha Canada entered into a license agreement with Neurodyn Life Sciences Inc. (“**Neurodyn**”), as amended November 4, 2020, pursuant to which it acquired the world-wide exclusive rights to the ALPHA-0602 technology.

On July 9, 2020, the Company and Alpha Canada entered into a letter agreement, pursuant to which the Company proposed to acquire 100% of the issued and outstanding shares of Alpha Canada.

On October 27, 2020, the Company and Alpha Canada entered into the definitive arrangement agreement to formalize and replace the letter agreement.

On November 3, 2020, Alpha Canada entered into a royalty agreement with respect to ALPHA-0602 made between Neurodyn Life Sciences Inc., Andrew Bateman Ph.D., Hugh P.J. Bennett Ph.D., Babykumari Chitramuthu Ph.D. and Denis Kay Ph.D.

On December 18, 2020, and February 10, 2021, the Company and Alpha Canada completed the partially brokered private placement of 3,360,124 subscription receipts of the Company and Alpha Canada at price of \$1.60 per subscription receipt for aggregate gross proceeds of approximately \$5,376,198 (US\$4,042,254 using a set exchange rate of \$1.33 to US\$1).

On March 18, 2021, the Company completed its Qualifying Transaction with Alpha Canada and changed its name to Alpha Cognition Inc. As a result of the Qualifying Transaction, Alpha Canada became the Company's wholly-owned subsidiary.

On April 12, 2021, the Company announced the appointment of Mr. Michael McFadden as Chief Executive Officer and the appointment of Mr. Len Mertz as Chairman.

On April 27, 2021, the Company announced the appointment of Ms. Colleen Johns as Senior Vice President, Product Development, as part of the Company's plan to further develop the operational and commercialization team.

On May 4, 2021, the Company announced the appointment of Ms. Lauren D'Angelo as Chief Commercial Officer, as part of the Company's plan to further develop the operational and commercialization team.

Effective as of August 18, 2021, the Company's Common Shares were approved for quotation on the OTCQB Venture Market under the symbol "ACOGF".

On September 7, 2021, the Company announced that the FDA accepted its Investigational New Drug application for lead candidate, ALPHA-1062 for the treatment of Alzheimer's Disease to proceed to the pivotal clinical phase of the development program. This set of bioavailability-bioequivalence trials, if successful, would allow the Company to submit a new drug application for ALPHA-1062 in 2023. ALPHA-1062 is being developed as a next generation of acetylcholine esterase inhibitor (AChEI) designed to improve upon the existing standard of care by overcoming gastrointestinal side effects and tolerability limitations.

On October 1, 2021, the Company completed a prospectus offering for aggregate gross proceeds of approximately \$14.4 million through the issuance of 9,602,500 units at a price of \$1.50 per unit. Each unit consists of one common share of the Company and one common share purchase warrant. Each warrant entitles the holder to acquire an additional common share of the Company at a price of \$1.75 per share until October 1, 2023. The warrants issued in connection with the prospectus offering began trading on the TSX-V under the symbol "ACOG.WT" effective as of October 5, 2021 (the "**Listed Warrants**").

On October 1, 2021, the Company announced the formation of its Scientific Advisory Board, and that it had engaged Bello Capital Partners to provide strategic digital media services and also engaged Wealth Securities Limited as a market-maker.

On December 2, 2021, the Company announced the appointment of Dr. Cedric O'Gorman as Chief Medical Officer, to lead the medical, clinical and regulatory functions in support of the Company's clinical-stage products, ALPHA-1062 and ALPHA-0602. Dr. O'Gorman ceased to act as the Chief Medical Officer effective as of January 1, 2023.

On December 6, 2021, the Company announced the results from their ALPHA-1062 preclinical neurobehavioral and cognitive study. The study found that ALPHA-1062 achieved statistically significant improvement as compared to injured but untreated animals in every primary endpoint and achieved results equal with uninjured animals in four of five neuro-behavioral primary endpoints. Animal body weight was unaffected in the study. Additional histology work will be done to complete the trial. Pending results of the study and a meeting with the FDA, the Company could advance the program to a second mammal or directly to a Phase 2 clinical trial in humans. All Phase 1 trial work has been completed with positive results.

On December 28, 2021, the Company announced that Dr. Fred Sancilio resigned from his role as a director and as President of the Company.

On March 29, 2022, the Company announced positive preclinical data from their ALPHA-0602 ALS gene therapy program. The data underscores the robust preclinical evidence supporting the Company's adeno-associated virus (AAV) based gene therapy approach to treating ALS and highlights the Company's strategy to validate these data in planned clinical trials.

On April 12, 2022, the Company announced the appointment of Don Kalkofen as Chief Financial Officer of the Company and the addition of Michael McFadden, the Company's Chief Executive Officer, to the Board.

On April 28, 2022, the Company announced the following program developments:

- ALPHA-1062 for mild to moderate dementia of the Alzheimer's type
  - The Company has initiated pivotal trials to demonstrate bioequivalence to the FDA-assigned reference listed drug, required for marketing approval. The trials are of a single dose, cross-over study design in both fed and fasted conditions.
  - The Company intends to meet with the FDA to discuss the ongoing clinical development of ALPHA-1062 and a proposed Alzheimer's Disease tolerability and dosing trial which could allow for prescribing information changes post-approval. Pending regulatory feedback, the plan would be to initiate this study in late Q2 2022, with top line results expected in 2023.
  
- ALPHA-0602 for ALS
  - The Company announced positive preclinical data from its ALPHA-0602 ALS gene therapy program. These data underscore the robust preclinical evidence supporting the Company's adeno-associated virus (AAV) based gene therapy approach to treating ALS and highlights 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 progranulin expression in motor neurons, suggesting a neurotrophic role for progranulin. ALPHA-0602 further increased progranulin 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 progranulin, ALPHA-0602 reversed the motor neuron toxicity resulting from 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 transactive response DNA binding protein 43 kDa ("TDP-43"), ALPHA-0602 administered via adeno-associated virus, resulted in successful viral transduction of central nervous system cells and substantially increased cerebrospinal fluid levels of progranulin.

- 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.
- ALPHA-1062 for mTBI
  - The Company announced functional data from the ALPHA-1062 mTBI program. ALPHA-1062 intranasal administration significantly reduced the extent of the functional deficit, and improved functional recovery of mTBI animals compared to untreated animals suffering a mTBI. Notably, in four of five functional measures of recovery, the performance of ALPHA-1062 treated group was statistically indistinguishable from that of the uninjured cohort.
  - In a rodent model of mTBI, ALPHA-1062 or vehicle (purified water as treatment control) was administered intranasally, with treatment initiated two 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 assessments; and
    - improved cognitive functional recovery measured by tests which assess recognition memory, and spatial learning and memory.
  - The Company announced histology data from the intranasal ALPHA-1062 mTBI 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 mTBI.

On May 31, 2022, the Company announced that during the second quarter of 2022, the Company met with the FDA regarding the ALPHA-1062 program for mild-to-moderate Alzheimer’s Disease. The Company received feedback regarding the ALPHA-1062 trial, labeling, and manufacturing. The Company also received pediatric designation for ALPHA-0602 for treatment of spinal muscular atrophy. This designation allows for priority review.

On May, 31, 2022 the Company also announced the grant of stock options pursuant to its stock option plan to certain directors of the Company to purchase up to an aggregate of 400,000 Common Shares of the Company. The stock options are exercisable at a price of \$0.64 CAD per share and expire ten years from the date of grant, subject to certain vesting provisions.

On June 22, 2022, the Company announced positive results from its pivotal bioequivalence study with ALPHA-1062 for the treatment of mild to moderate Alzheimer’s. The study was designed to demonstrate pharmacokinetic equivalence compared to the reference listed drug “galantamine hydrobromide” immediate release, which is a standard of care treatment for patients with mild to moderate Alzheimer’s Disease. 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” in the fed state. Data were within the required pharmacokinetic range of prior data demonstrated with “galantamine hydrobromide”. There were no adverse events reported for ALPHA-1062 during these studies. With these positive pivotal study results, the Company plans to file an NDA for ALPHA-1062 in mild to moderate Alzheimer’s in Q3 2023.

On August 22, 2022, the Company announced positive topline results from a bioequivalence study with ALPHA-1062. The Company elected to conduct this additional study which was designed to demonstrate pharmacokinetic (PK) equivalence between 5mg ALPHA-1062 delayed release tablets and 8 mg galantamine hydrobromide extended release capsules. These data, coupled with the positive pivotal data released in June, establish bioequivalence to both formulations (immediate and extended release) of galantamine hydrobromide and strengthen the NDA application for ALPHA-1062 in mild-to-moderate Alzheimer's Disease, planned for Q3 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 extended release. 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 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.

On August 25, 2022, the Company announced Q2 results and provided a corporate update including the following:

- The Company elected to conduct this additional study which was designed to demonstrate pharmacokinetic (PK) equivalence between 5mg ALPHA-1062 delayed release tablets and 8 mg galantamine hydrobromide extended release capsules. 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 Q3 2023.
- The Company has completed significant start-up activities in preparation to initiate the RESOLVE tolerability study to date. The Company is seeking additional capital to fund this study initiation and will commence the study within a quarter to securing the required funding.
- The Company has initiated cost cutting measures to lower its near-term burn rate. The Company streamlined R&D programs to focus on ALPHA-1062 and reduced headcount and other operating costs not essential to the ALPHA-1062 NDA file.
- The Company plans to request an FDA meeting to discuss the clinical development of intranasal ALPHA-1062 for the treatment of cognitive impairment with TBI. It is anticipated that this meeting will take place in Q4 2023.

On November 28, 2022, the Company provided the following corporate updates:

- The Company continues to prepare its NDA filing for ALPHA-1062 for mild to moderate Alzheimer's Disease.
- The Company completed an additional steady state bioavailability-bioequivalence study which was designed to demonstrate pharmacokinetic (PK) equivalence between 5mg ALPHA-1062 delayed release tablets and 8 mg galantamine hydrobromide extended release capsules.
- 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, which is planned for Q3 2023.

- The Company implemented cost cutting measures to lower its near-term burn rate. The Company streamlined research and development programs to focus on ALPHA-1062 and reduced headcount and other operating costs not essential to the ALPHA-1062 NDA file.

Below is a description of the Company's developments subsequent to the financial year ended December 31, 2022:

- On January 19, 2023, the Company announced the cancellation of 4,655,000 incentive stock options with exercise prices ranging from \$0.64 to \$1.05, and granted 4,655,000 incentive stock options to certain directors and officers of the Company at an exercise price of \$0.28 per share.
- On February 16, 2023, the Company announced that it had closed the first tranche of a private placement of units and issued 16,795,221 units of the Company at a price of \$0.255 per unit for gross proceeds of \$4,282,781. On March 15, 2023, the Company announced that it had closed the second tranche of a private placement of units and issued 6,952,427 units of the Company at a price of \$0.255 per unit, for gross proceeds of \$1,772,869. Each unit comprises a Common Share and a share purchase warrant. Each warrant entitles the holder to purchase one additional common share of the Company at a price of \$0.39 (approx. US\$0.29) per share for a period of five years. The private placement financing raised gross proceeds of C\$6.1 million (US\$4.5 million) through the sale of an aggregate 23,747,648 units. The Company expects to use the net proceeds, together with its existing cash, cash equivalents and investments, for the advancement of the Company's clinical development programs, complete and file the NDA for ALPHA-1062, and for working capital and other general corporate purposes. In connection with the offering the Company engaged Spartan Capital Securities, LLC ("**Spartan**") of New York, which received compensation for its services on closing of the offering of US\$172,480 in cash, 2,129,566 Common Shares, and 324,642 warrants having the same terms as the unit warrants. Spartan is a U.S. brokerage firm registered in all states and territories of the U.S.
- On March 1, 2023, Alpha Canada and Neurodyn agreed to an amendment to the US\$1.2M 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 is effective March 1, 2023 and requires monthly interest only payments until maturity. In addition, the amendment now incorporates the Company as a party to the ALPHA-1062 license agreement and added clarity to certain terms and definitions.
- On April 27, 2023, the Company received final approval from the CSE to list its Common Shares and the Listed Warrants on the CSE. The Company also announced that it would voluntarily delist the Common Shares and Listed Warrants from the TSX-V. The TSX-V delisting took effect at the close of business on April 28, 2023 and the Common Shares and Listed Warrants were listed for trading on the CSE effective as of May 1, 2023. The Company now trades its Common Shares under the symbol "ACOG" and Listed Warrants under the symbol "ACOG.WT" on the CSE.
- On May 30, 2023, the Company announced a best efforts private placement offering of up to US\$6,500,000 of units at a price of US\$0.22 per unit. Each unit consists of one common share and one-half of a Warrant. Each whole Warrant will entitle the holder to purchase an additional Common Share of the Company at a price of US\$0.31 per share for a period of three years from the closing date.

In connection with the offering, the Company entered into an investment banking agreement (the “**IBA**”) with Spartan, pursuant to which Spartan will act as agent. Pursuant to the IBA, Spartan was granted an over-allotment option to increase the total amount of the offering by up to 30% upon mutual agreement of the Company and Spartan. Pursuant to the IBA, the Company has agreed to pay Spartan a cash commission of 10% of the gross proceeds of the offering, and compensation 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. Spartan is also entitled to a non-accountable expense fee equal to 5% of the gross proceeds of the offering excluding the president’s list.

The Company and Spartan also entered into a consulting agreement (the “**Consulting Agreement**”), pursuant to which Spartan agreed to provide ongoing consulting services for a three year term. The services will include advising and assisting on potential business development transactions, strategic introductions, assisting management with enhancing corporate and shareholder value, and providing capital raising advice. The Company will pay Spartan a consulting fee in the aggregate amount of US\$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. Pursuant to the Consulting Agreement, the Company expects to appoint a director nominated by Spartan following completion of the offering, which may be increased to two nominees upon completion of a business development transaction with Spartan’s involvement.

- Also on May 30, 2023, the Company announced Q1 results and provided a corporate update including significant progress in the completion of an NDA filing for ALPHA-1062 targeting mild to moderate Alzheimer's disease. The Company also shared the following objectives for 2023:
  - file an NDA for ALPHA-1062 in mild-to-moderate Alzheimer’s Disease during the third quarter of 2023, with possible FDA approval for the U.S. market by Q3 2024;
  - continue to advance its development and commercialization activities for ALPHA-1062 in mild-to-moderate Alzheimer’s Disease, including program development and clinical manufacturing for ALPHA-1062;
  - meet with FDA on the Company’s R&D program for Cognitive Impairment with mTBI at a pre-IND meeting; and
  - pursue the out-licensing of its TBI indication to a newly formed and funded company (the “**TBI Company**”), where the TBI indication can be further developed. The TBI Company would focus on the advancement of ALPHA-1062 for the treatment of Cognitive Impairment with mTBI using an intra-nasal formulation (ALPHA-1062IN), including advancing clinical trials with the goal of FDA approval. The establishment of the TBI Company would provide for separate funding and advancement of the TBI applications of ALPHA-1062IN while permitting the Company to remain focused on advancing ALPHA-1062 for use in the treatment of symptoms of Alzheimer’s Disease.

- On June 7, 2023, the Company announced that it was awarded a US\$750,000 grant from the Army Medical Research and Materiel Command (AMRMC) for a pre-clinical study on the use of ALPHA-1062 to reduce blast mTBI induced functional deficit and brain abnormalities. The study grant will be issued by AMRMC and conducted in collaboration with the Seattle Institute for Biomedical and Clinical Research (SIBCR) and is endorsed by Department of Defense (DOD). The aim of the study is to evaluate the efficacy of ALPHA-1062IN in reducing the adverse effects of repetitive blast induced-mTBI in pre-clinical models.
- On June 8, 2023, the Company announced the grant of stock options pursuant to its stock option plan to certain directors, officers and employees of the Company to purchase up to an aggregate of 16,190,000 Common Shares of the Company. The stock options are exercisable at a price of C\$0.22 per share and expire ten years from the date of grant, subject to certain vesting provisions.

## DESCRIPTION OF THE BUSINESS

### General

The Company is a clinical stage, biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's Disease and cognitive impairment with TBI, 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 with a near-term goal of NDA submission and FDA approval and 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 intranasal formulation for the treatment of mild cognitive impairment with TBI, and ALPHA-0602, previously referred to as 'Progranulin', for the treatment of amyotrophic lateral sclerosis, otherwise known as ALS or Lou Gehrig's disease.

ALPHA-1062, is a patented new chemical entity 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 and as an intranasal formulation for cognitive impairment with TBI.

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.



## Business Objectives and Milestones

The Company's principal business objectives are to: 1) file an NDA for ALPHA-1062 in mild-to-moderate Alzheimer's disease; 2) continue to advance its development and commercialization activities for ALPHA-1062 in mild-to-moderate Alzheimer's disease, including the clinical trial program development and clinical manufacturing for ALPHA-1062, 3) Meet with FDA on TBI R&D program at a pre-IND meeting; complete IND submission if aligned with FDA, and 4) pursue the out-licensing its TBI indication to the TBI Company, a newly formed and funded company, where the TBI indication can be further developed.

In order to meet these business objectives, the Company will need to initiate or complete the following milestones in the same 12-15 month period:

- File the NDA Package ALPHA-1062 - The Company will prepare a complete NDA package for ALPHA-1062 in mid-to-moderate Alzheimer's disease to submit to the FDA for drug approval and subsequent commercialization. The Company will meet with the FDA at a pre-NDA meeting to review and discuss the package details and align with FDA expectations. The Company plans to file the NDA package with the FDA in the third quarter of 2023 timeframe. The NDA package will include the preclinical studies, clinical studies, manufacturing and controls, regulatory, quality and any other data necessary for the FDA to review ALPHA-1062 for US approval. Costs for NDA filing are expected to include regulatory and CMC preparation, medical writing, and submission to FDA in its required format.
- 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 target markets, customer types to prioritize, resources to utilize, commercialization positioning, marketing messages, and operational plans post approval.
- ALPHA-1062 US product approval for treatment of mild-to-moderate Alzheimer's disease – The Company will negotiate the commercial label and approval of the product with FDA, which is anticipated in Q3 2024. If approved, this would be one of four products approved for Alzheimer's disease in the last 14 years. The approval would represent a next generation oral treatment for disease that ameliorates symptoms of Alzheimer's disease. Approval could provide the Company with significant new business opportunities for commercial and/or development partners.

- Obtain IND for ALPHA-1062 Intranasal for TBI – The Company will meet with the FDA to obtain approval for IND ALPHA-1062 Intranasal for TBI. The Company will engage the FDA in a pre-IND meeting in Q2, 2023 and will seek approval to file IND for a second indication. The FDA grants IND's when all preclinical work is completed to enter into human subjects. The Company will prepare a synopsis of all preclinical study work and show the FDA PH1 studies for ALPHA-1062 Intranasal where the medicine was tested for Alzheimer's disease. If the FDA agrees that an IND is appropriate, the Company will complete the required request for IND and could have an approved IND by December 2023. This would provide the Company business development opportunities to partner the asset with another strategic company or license the indication to another neuroscience company. The cost to complete the work and obtain an IND is <\$100,000 and could provide inflection points from a business development standpoint.
- ALPHA-1062 Intranasal for TBI out-licensing – The Company plans to out-license the TBI asset into the TBI Company and raise additional capital for the TBI Company specific to advance the TBI program. The Company and its subsidiaries would initially make up the largest shareholder of the TBI Company, but the Company anticipates that all shareholders will be diluted as new capital is raised for research and development. The amount of dilution will be determined by capital raised and valuation of the TBI Company. The Company intends to include the following in the TBI out-license agreement with the TBI Company: intellectual property specific to TBI, implementation of a data sharing agreement, and supply and comprehensive maintenance agreements for technology advancements. The Company also intends to utilize existing Company management and new consultants experienced in TBI research and development to staff the TBI Company. The Company is planning to request a pre-IND meeting with the FDA to discuss our clinical development plan in Q2, 2023. If successful in raising capital for this program, the TBI Newco would initiate a trial, in alignment with FDA feedback, for the treatment of Cognition Impairment with mild traumatic brain injury (TBI) in Q4 2023. If successful, the advancement of this program in 2023 will allow for potential inflection points for Alpha shareholders in 2023 (IND acceptance; first patient enrolled in trial) and in 2024 (Last patient enrolled, initial results).

The foregoing business objectives will be adjusted based on available funds. The Company may need to extend the estimated timeframe for achieving the milestones and objectives set out above if it does not complete additional financings.

### 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 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'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 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 plans to file 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
AUC <sub>0-inf</sub> (µg × h/mL) Fasted State	306.8	321.5	95%	✓	AUC <sub>0-24</sub> (µg × h/mL) Steady State	527.5	492.1	107%	✓
C <sub>max</sub> (ng/mL) Fasted State	30.7	40.5	76%	✓	C <sub>max</sub> (ng/mL) Steady State	41.7	32.8	127%	✓
AUC <sub>0-inf</sub> (µg × h/mL) Fed State	286.7	329.9	87%	✓					
C <sub>max</sub> (ng/mL) Fed State	27.6	30.2	91%	✓					

- Data confirms **ALPHA-1062 AUC is bioequivalent to galantamine hydrobromide IR and ER**
- C<sub>max</sub> 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. SA Customer: <https://www.fda.gov/oc/oaq/oaq-submitted-bioequivalency-and-bioequivalency-studies-submitted-in-NDAs-or-INDs>

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### 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 C<sub>max</sub>, 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 C<sub>max</sub> 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, planned for Q3 2023. The Company is preparing to file the NDA with the FDA.

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 now plans to file 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.

RESOLVE Tolerability Study: Following NDA approval for ALPHA-1062 in mild to moderate Alzheimer's Disease, 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. While not required for ALPHA-1062 NDA approval, RESOLVE data would be utilized to enhance the commercialization of ALPHA-1062. Significant trial preparation has already been completed. Processes and data management support has been established, and a number of potential sites have been identified, evaluated, qualified and readied for activation. Institutional Review Board approval has been received and the final study protocol has been submitted to the IND. The Company expects to initiate its RESOLVE trial in Q4 2024, following NDA approval of ALPHA-1062 and securing additional capital.

mTBI: The Company has also completed a pre-clinical study of ALPHA-1062 in mTBI. The Company is encouraged by the preclinical data and is planning to request a meeting with the FDA in Q3 2023 to discuss IND submission and further clinical development plans. Pending FDA feedback, the Company is targeting the IND submission for intranasal ALPHA-1062 for mTBI in Q4 2023.

In December 2021, the Company announced functional data from the ALPHA-1062 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 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.

### TBI Out-Licensing Plan

The Company is proposing to out-license the limited use of ALPHA-1062 solely for applications in treating mTBI and TBI to a new entity (the “**TBI Company**”). The TBI Company expects to focus its business on the advancement of the use of ALPHA-1062 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 the TBI Company would provide 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.

Spartan has agreed to act as agent, on a best efforts basis, for financing the TBI Company in exchange for an initial 37.5% ownership interest in the TBI Company, with the Company initially retaining 47.5% ownership and key management of the TBI Company (the “**TBI Management**”) holding the remaining 14.6% ownership interest, and 0.4% for future directors of the TBI Company. While the Company and its subsidiaries would initially make up the largest shareholder of the TBI Company, but it is anticipated that all TBI Company shareholders will be diluted as new capital is raised for research and development. The amount of dilution will be determined by capital raised and valuation of the TBI Company. Spartan’s interest will be subject to completion of an initial financing for gross proceeds to the TBI Company of no less than US\$1 million. TBI Management’s ownership will be granted and issued up front, subject to the completion of a one year term of service. Should a member of the TBI Management team resign their position prior to completion of the full one year term, 1/13th of the total shares granted and issued to such executive will be required to be returned to the Company and cancelled for each full month not completed

of the term. TBI Management is expected to be as follows: Michael McFadden, the Chief Executive Officer and a director of the Company, is expected to serve as Chief Executive Officer of the TBI Company, Donald Kalkofen, the Chief Financial Officer of the Company is expected to serve as Chief Financial Officer of the TBI Company, and Lauren D'Angelo, the Chief Commercial Officer of the Company, is expected to serve as Chief Business Officer of the TBI Company.

The Company is planning to request a pre-IND meeting with the FDA to discuss our clinical development plan in Q2 2023. If successful in raising capital for this program, the TBI Newco would initiate a trial, in alignment with FDA feedback, for the treatment of Cognition Impairment with mild traumatic brain injury. The establishment and funding of the TBI Company as described above are at the proposal stage only. There is no guarantee that the Company will be successful at launching the TBI Company as a separately funded entity as described above or at all. If successfully launched, there is no guarantee that the TBI Company will be successful in advancing the ALPHA-1062 for use in TBI or mTBI.

### ALPHA-1062 Alzheimer's Disease 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 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 Neurology and Long Term Care (LTC) physicians in the U.S. 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 U.S. from these two specialties is large, representing 63% of the over 11 million prescriptions filled in pharmacies each year. The AChEI class includes Aricept, Exelon, Exelon Patch, Razadyne, Adlarity, 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 within one year. The Company believes that patients who discontinue a first therapy will try a 2nd and 3rd 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 deploying a highly targeted and efficient multi-channel marketing campaign, by motivating caregivers to request ALPHA-1062, and 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 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 researchers at McGill University in Montreal discovered 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 or 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 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 and 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 the Company'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 central nervous system 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 the Company's approach to treating neurodegenerative disease and highlight the Company's strategy to validate these data in additional pre-clinical studies. The Company has paused further development with GEM's and ALPHA-0602 in order to focus all resources toward ALPHA-1062 clinical and regulatory development.



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.
- Future studies will seek to 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 completed in Q3 2022. The Company will look to meet with community experts in the development of a toxicology program and an appropriate in vivo disease model to provide proof of efficacy. Following this the Company intends to seek FDA guidance regarding, relevant pre-clinical safety studies to be initiated in animal models consistent with 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 up to US\$3,200,000.

The Company has received Rare pediatric designation for ALPHA-0602 for treatment of spinal muscular atrophy. This voucher could 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.

#### *Specialized Skill and Knowledge*

The development of pharmaceutical products is a complex undertaking which requires many diverse skill sets. Given the international nature of drug development, there are numerous companies and organizations which service the pharmaceutical industry. The Company has had no difficulty to date contracting with the various specialized service providers required to complete a drug development program.

The Company has assembled a management team capable of overseeing the various contract development, manufacturing organizations which have been retained to assist the Company in the ALPHA-1062 development program. The Company is also in the process of assembling a commercialization team with the experience and skills necessary to commercialize ALPHA-1062, should it be approved.

### *Competitive Conditions*

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 data, 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 U.S. 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

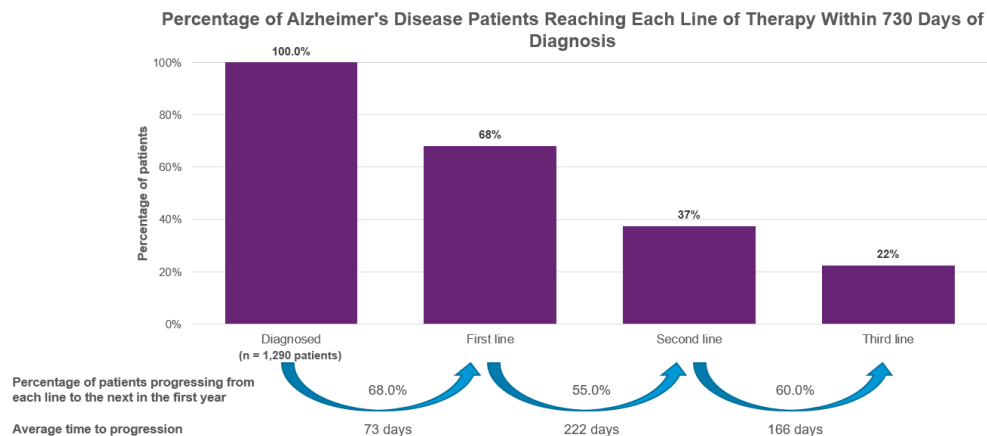
The FDA recently approved Aducanumab (marketed under the branded name Adulhelm® by Biogen) and lecanemab (marketed under the branded name Leqembi® by Eisai) for mild-to-moderate Alzheimer's Disease. Adulhelm was the first disease modifying treatment (DMT), but due to several issues associated with the 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.

Approved in 2022 was Adlarity® (donepezil transdermal system), by the marker Corium. It is a once-weekly patch formulation of donepezil for the treatment of dementia due to mild, moderate, or severe Alzheimer's Disease. The Company believes Adlarity® would likely be ALPHA-1062's primary branded competitor. The real unmet need in the marketplace exists for a symptomatic treatment that has a better

tolerability profile. The Adlarity® label has its disadvantages as it relates to its' tolerability profile. The Company believes that Adlarity®'s profile has exchanged gastrointestinal side effects for skin irritation issues and headache, which may not be tolerated well by this patient population. Notable adverse reactions in their label are skin irritations 81%, headache 15%, and insomnia 7%. The Company also believes Adlarity®'s tolerability profile and transdermal delivery system is not ideal for elderly patients, as their fragile skin is sensitive and susceptible to tears and abrasions. The Alzheimer's Disease community has learned this firsthand with rivastigmine (Exelon patch). 72% of caregivers noted the rivastigmine patch causes skin irritations issues for their loved one. With this feedback, we believe the oral delivery of ALPHA-1062 will be more convenient and a better option for these patients. Additionally, Adlarity® storage, application and removal process may be burdensome to elderly patients and caregivers. Adlarity® must be stored in a refrigerator until use, warm up to room temperature prior to use, can not be applied to the same body location within 14 days and can not be exposed to excess heat, such as a heating pad. The Company predicts these storage and usage requirements will be seen as inconvenient and coupled with the adverse reactions, will limit market share attainment of this product.

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 (ie: 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



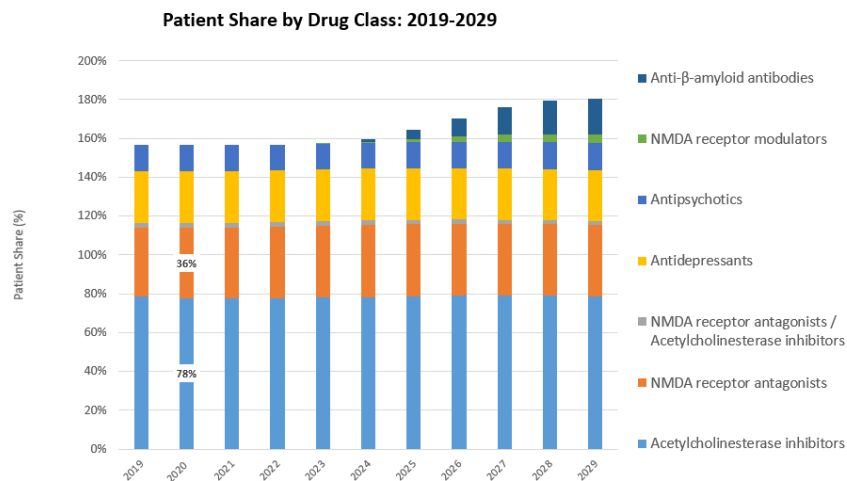
Source: Decision Resources Group, 2021

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 specialty physicians and 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 express dissatisfaction with the currently approved symptomatic treatments options.

### *Acetylcholinesterase Inhibitors*

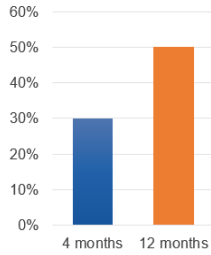
As mentioned, acetylcholinesterase inhibitors are the dominant symptomatic drug class, which inhibit cholinesterase and prevent the breakdown of acetylcholine in the brain. They account for approximately 80% of all Alzheimer's Disease drug prescriptions, which equates to 11 million prescriptions each year and \$5B in sales dollars (assuming branded priced market). The use of acetylcholinesterase inhibitors as the go-to medication is forecasted to remain consistent well into the future. Donepezil is the staple acetylcholinesterase inhibitor, with approximately 70% total market share.



*Source: AD Landscape, 2021*

Yet, according to the market research, physicians believe donepezil has reported little clinical improvement and a less than desirable tolerability profile. So, their treatment choice to prescribe it is based on secondary attributes: longevity in the market, low generic cost and once-daily dosing. Physicians and caregivers report 56-78% of the time donepezil tolerability issues are the primary reason for discontinuation. Caregivers perceive these side effects diminish their loved one's quality of life in terms of comfort, eating, and ability for independent toileting. In addition to gastrointestinal issues, long-term care physicians in particular note that nausea and loss of appetite are troublesome side effects because it affects the patient's ability to socialize, disrupts mealtimes and causes family complaints. Additionally, the gastrointestinal issues cause staff burden due to the risk of falls as the patient tries to rush to a bathroom. Physicians and caregivers cite that approximately 40% of the time perceived limited efficacy results or not enough efficacy improvement is the second reason patients discontinue therapy. Increasingly worrisome, as noted in research, is that over half of patients that discontinue donepezil within long-term care homes are not prescribed another Alzheimer's Disease medication. This could result in a patient's disease progressing at a rapid pace without any treatment assistance. Another limitation of the acetylcholinesterase inhibitors is the long titration schedule (4-6 weeks) to reach the maximum efficacious dose. Needless to say, improved efficacy outcomes, a shorter titration schedule and a better tolerability profile are significant unmet needs for future Alzheimer's Disease treatments.

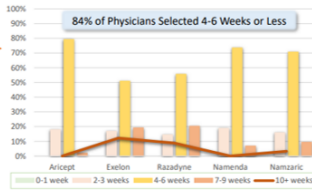
**High discontinuation rates of current therapies**



**56%-78% of discontinuation of Donepezil is due to tolerability side effects**

Reasons for Donepezil Discontinuation	HCP	LTC	Care giver
% Perceived lack of efficacy/deemed "unnecessary medication"	42%	52%	36%
% GI adverse effects	34%	50%	36%
% Non-GI adverse effects/dizziness	22%	22%	42%

**Average Length in Weeks for Up-titration Step**



Source: 2 Infinity Group, Market Research, 2021

*Forecasted Alzheimer’s Disease Treatments*

More than 126 drugs are currently in various stages of development for Alzheimer’s Disease and the treatments range from symptomatic, disease modifying, and behavioral. Despite the forecasted launches of DMTs, assuming clinical success and FDA approval, symptomatic therapies (specifically acetylcholinesterase inhibitors) will still be a dominant therapy and maintain the largest Rx share in an Alzheimer’s Disease patient’s treatment algorithm. Symptomatic therapies and DMTs, are projected to be used in combination to maximize efficacy and symptom control for Alzheimer’s Disease patients.

There are currently 74 Alzheimer’s Disease treatments in phase 2 clinical trials and 28 treatments in Phase 3, a number of which are projected to be approved for mild-to-moderate stages of Alzheimer’s Disease. Eli Lilly’s solanezumab, Merck’s verubecestat, and Taurz therapeutics LMTX. If approved and commercialized, these disease modifying treatments are projected to increase the rates of Alzheimer’s Disease diagnosis and treatment. While there should be much anticipation for their potential approvals, the regrettable circumstances surrounding the real-world obstacles that Biogen faced with the approval of Aduhelm® have caused the Alzheimer’s Disease community to be apprehensive. Physicians are skeptical about disease modifying treatment usage due to the lack of available information to date, the anticipated cost and reimbursement challenges, and concerns about their real-world efficacy results.

Within the behavioral drug category, four therapies targeting key neuropsychiatric symptoms are expected in the coming years and will expand the Alzheimer’s Disease treatment market. Expected launches include Avanir/Otsuka’s AVP-786 (agitation with Alzheimer’s dementia), and Axsome’s AXS-05 (agitation with Alzheimer’s dementia). According to Key Opinion Leaders and market research, these treatments would likely be used in combination with indicated symptomatic treatments, such as ALPHA-1062, in Alzheimer’s Disease patients experiencing neuropsychiatric symptoms. We also believe that the approval of these medications will likely increase Alzheimer’s Disease diagnosis and treatment rates, which is positive for potential ALPHA-1062 Alzheimer’s Disease patients.

*Intellectual Property*

The Company has developed, filed, and exclusively licensed (from Neurodyn) a significant intellectual property portfolio with respect to ALPHA-1062 and ALPHA-0602, which is broadly described below.

### ALPHA-1062 Patent Portfolio

The ALPHA-1062 patent portfolio is based on a therapeutic use (method of treatment) patent for ALPHA-1062, that covers treatment of a variety of neurological diseases with a cholinergic deficit, being memory deficits related to the cholinergic neurons, or brain disease with cognitive impairment. The Company's intellectual property strategy builds on this patent by avoiding traditional fast-release oral or transdermal routes for administering ALPHA-1062. Both routes would result in the premature cleavage of the pro-portion of the ALPHA 1062, in essence delivering the old drug (galantamine) with its attendant limitations. However, by transmucosal oral/nasal delivery or delayed release via enteric formulations, effective delivery of ALPHA-1062 can be achieved. Delivery, polymorph, and formulation patents therefore effectively expand on the original therapeutic use patent. It is the Company's intent to patent all commercially relevant forms, formulations and routes/methods of ALPHA-1062 delivery in order to extend the effective patent protection lifetime. There is potential that effective patent protection of ALPHA-1062 and therapeutically relevant salts, polymorphs and/or formulations thereof can be extended beyond 2042.

The Company's current patents (granted and in prosecution) for ALPHA-1062 are listed below. The Company anticipates filing a number of future patents for ALPHA-1062 focused on active pharmaceutical ingredient manufacturer and formulation.

*Blood Brain Barrier II (BBB II):* Cholinergic enhancers with improved blood-brain barrier permeability for the treatment of diseases accompanied by cognitive impairment (PCT application WO2009127218).

<b>Jurisdiction</b>	<b>Patent number</b>	<b>Status</b>	<b>Expiry Date</b>
Canada	CA 2,721,007	Granted	04/2028
China	ZL200880128608.5	Granted	04/2028
Japan	JP 5504253	Granted	04/2028
Europe (11 European Patent Convention member states)	EP 2137192	Granted	04/2028
United States	US 9,763,953, US 10,265,325	Granted	12/2026

In Europe, Japan, China and Canada, this patent protects the therapeutic use of ALPHA-1062 to treat a variety of neurodegenerative, psychiatric or neurological diseases with a cholinergic deficit. In the United States two patents are allowed in this patent family that cover the corresponding method of treatment claims, one of which is directed to nasal administration of ALPHA-1062.

Patent term extension (PTE) of U.S. 9,763,953 appears likely, assuming FDA approval of the gluconate salt of ALPHA-1062 is achieved. An application requesting PTE must be filed within sixty days of FDA regulatory approval of the ALPHA-1062 drug product. The duration of a PTE may not exceed five (5) years, and the patent cannot be extended such that it would expire, with PTE, more than 14 years after the date of the underlying FDA approval. Considering the 5-year maximum, the 14-year limit will likely not apply to the '953 patent due to its nominal expiry date (in 2026). A 5-year extension could extend patent term until 2031. A more detailed estimate of the duration of PTE will require a detailed analysis of the timeline of the regulatory approval process.

*Blood Brain Barrier III (BBB III):* Enhanced bioavailability of galantamine by selected formulations and trans-mucosal routes of administration of lipophilic prodrugs (PCT application WO2014016430).

<b>Jurisdiction</b>	<b>Patent number</b>	<b>Status</b>	<b>Expiry Date</b>
Australia	AU 2013294917	Granted	07/2033

Jurisdiction	Patent number	Status	Expiry Date
Europe (11, and 18, European Patent Convention member states)	EP 2877165 and EP 3417862	Parent and Divisional Granted	07/2033
Japan	JP 6272857, JP 6574002 and JP 6799648	Parent and two Divisionals Granted	07/2033
Canada	CA 2,878,135	Granted	07/2033
United States	US 11,077,119 US 16,287,413	Granted and Pending Continuation	07/2033 -

The granted claims in the jurisdictions above are directed to the therapeutic use of ALPHA-1062 and corresponding pharmaceutical compositions in the treatment of brain disease associated with cognitive impairment, wherein the claims cover intranasal, sublingual or buccal administration of the gluconate, saccharate or lactate salt of ALPHA-1062. Divisional applications have been filed and issued in some jurisdictions (e.g. in Japan and Europe) to cover these embodiments. In the U.S. the patent has been granted for sublingual administration, a continuation application is pending, further divisional and continuation applications are intended.

*Blood Brain Barrier IV (BBB IV):* Self-preserving compositions and multi-use dispensers for administering ALPHA-1062 (PCT application PCT/CA2021/050666).

Jurisdiction	Patent number	Filed	Status	Expiry Date
PCT application filed	PCT/CA2021/050666	05/2021	Pending	2041

This invention is based on the discovery that ALPHA-1062 exhibits potent anti-microbial properties. This effect enables self-preserving formulations, for example multi-use solutions or dispensers for oral/nasal transmucosal administration, without additional preservatives. The claims cover anti-microbial methods, multi-use delivery devices and corresponding formulations of ALPHA-1062.

*Blood Brain Barrier V (BBB V):* Solid Forms of ALPHA-1062 Gluconate

Jurisdiction	Patent number	Filed	Status	Expiry Date
European Priority filing	EP21152317	01/2021	Pending	2041
PCT application filed	PCT/CA2022/050046	01/2022	Pending	2042
United States	US 17/575025	01/2022	Pending	2042

This invention is based on the discovery and isolation of multiple unique crystalline forms of the ALPHA-1062 gluconate salt. A stable, highly soluble polymorph form was identified, which shows improved stability and solubility over other crystalline forms and is intended for use in the drug product. An international PCT application and parallel U.S. application were filed January 13, 2022, the European priority application also remains pending. The Canadian Intellectual Property Office (CIPO) has acknowledged novelty and inventive step of the claims of the PCT application.

*Blood Brain Barrier VI (BBB VI):* ALPHA-1062 for Treating mTBI

Jurisdiction	Patent number	Filed	Status	Expiry Date
European Priority filing	EP21210661.1	11/2021	Pending (not published)	2042

This invention is based on preclinical animal studies in TBI showing enhanced therapeutic benefit, suited for multi-use intranasal administration, building on the antimicrobial properties of the API. The European priority application remains pending. An international PCT-application is planned.

*Blood Brain Barrier VII (BBB VII): ALPHA-1062 for the Treatment of Mild to Moderate Impaired Cognitive Function in Neurologically Intact Elderly Subjects*

Jurisdiction	Patent number	Filed	Status	Expiry Date
European Priority filing	EP22170214.5	04/2022	Pending (not published)	2043

This invention is based on quantitative electroencephalography (qEEG) studies, showing that ALPHA-1062 affects several qEEG biomarker outcomes relevant to Alzheimer's Disease and cognitive functionality. ALPHA-1062 leads to long-lasting improvements on qEEG profiles consistent with positive effects on cognition, especially in neurologically intact subjects aged 65 or older. The European priority application remains pending. An international PCT application is planned.

*Additional IP is generated and in preparation for filing, including novel formulations and methods of synthesizing ALPHA-1062.*

#### ALPHA-0602 Patent Portfolio

The ALPHA-0602 patent portfolio is based on methods and compositions for the treatment of neurodegenerative diseases using progranulin, and a combination of effectors that modify progranulin expression. Issued patents include the use of both the full length progranulin and sequences to treat neurological diseases such as (in the European priority divisional) motor neuron disease including ALS, in addition to (the parent patent claiming) treatment of Alzheimer's and Parkinson's.

The Company's current patents (granted and in prosecution) for ALPHA-0602 are listed below.

*Progranulin For Use in Treating Parkinson's Disease or Alzheimer's Disease* (PCT application WO2009089635).

Jurisdiction	Patent number	Filed	Status	Expiry Date
China	CN102006882	1/16/2009	Granted	04/2028
India	280570	1/16/2009	Granted	04/2028
Europe (6 European Patent Convention member states)	2249861	1/16/2009	Granted parent and Divisional, Divisional maintained in opposition	04/2028
Canada	2,712,276	1/16/2009	Pending	06/2026
United States	16,851,951	1/16/2009	Pending	06/2026



The patent protects the therapeutic use of ALPHA-0602 to treat a variety of neurodegenerative, or neurological diseases. Alzheimer's Disease. A European Divisional patent was granted, covering the treatment of any neurodegenerative disease using progranulin and progranulin polypeptides, and methods of treatment of neurodegenerative diseases using effectors, or combinations of effectors, that modify progranulin expression.

It is the Company's belief that ALPHA-0602 will have seven year marketing exclusivity due to ALPHA-0602 Orphan Drug Designation in the U.S. Per FDA, a sponsor with orphan drug designation may be eligible for seven years of marketing exclusivity upon product approval. This exclusivity would prohibit FDA from approving the same drug as the orphan designated approved drug for the same use or indication for seven years after the marketing approval. (Code of Federal Regulations, or CFR Title 21 Part 316.31)

*Method for Increasing Nprilysin Expression and Activity* (PCT application WO2012065248A1).

Jurisdiction	Patent number	Filed	Status	Expiry Date
Japan	6312436	11/16/2011	Granted	11/2031

*Granulins or Combinations thereof to Treat Neurodegenerative Disease*

Jurisdiction	Application number	Filed	Status	Expiry Date
United States	US 63/191255	20/05/2021	Pending	05/2042

Ongoing development has found promising in vitro results for sub-combinations of progranulin fragments and GEMs. A U.S. provisional application has been filed.

### *Employees*

The Company currently has six employees/contractors in total. Employees and contractors work virtually and/or in offices located in Vancouver, BC; Charlottetown, PEI; Dallas-Fort Worth, Texas; and Weston, Florida. Employees utilize remote video conferencing and other connection tools to meet and advance business projects.

We recognize that our continued ability to attract, retain, and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- Talent development, compensation, and retention: We strive to provide our employees with a rewarding flexible and remote work environment. We provide a competitive compensation and benefits package, including bonus and equity incentive plans - all designed to attract and retain a skilled and diverse workforce.
- Health and safety: We support the health and safety of our employees by providing comprehensive insurance benefits, company-paid holidays, a personal time-off program, and other additional benefits which are intended to assist employees to manage their well-being.
- Inclusion and diversity: We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

### *Foreign Operations*

The Company's management team oversees the various contract development and manufacturing organizations which have been retained to assist the Company in the ALPHA-1062 and ALPHA-0602 development program, as further described below.

#### 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.

The Company believes it has completed all required phase 1 studies with ALPHA-1062 in mTBI.

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 AIF, 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.

### ***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's good laboratory requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board ethics committee, either centralized or with respect to each clinical site, before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice ("cGMP") requirements to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, and purity, and of selected clinical investigation sites to assess compliance with GCP;
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States;

- compliance with any post-approval requirements, including potential requirements to conduct any post-approval studies required by the FDA or the potential requirement to implement risk evaluation and mitigation strategies (“REMS”); and
- compliance with the United States *Pediatric Research Equity Act of 2003* (“PREA”), which requires either exemption from the requirements or may require conducting clinical research in a pediatric population.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 clinical trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

### ***NDA Review and Approval Process***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development nonclinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product’s identity, strength, quality, and purity. Under the Prescription Drug User Fee Act (“PDUFA”), guidelines that are currently in effect, the FDA has a goal of ten months from the date of “filing” of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a “filing” decision after the application is submitted. The FDA conducts a preliminary

review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

### ***Expedited Development and Review Programs***

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

### ***Post-Approval Requirements***

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on post-approval or Phase IV clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and the issuance of corrective information.

Under the PREA, an NDA must contain data to assess the safety and efficacy of the applicant product for indications in applicable pediatric populations. It must also contain information to support dose administration for pediatric populations where the drug may be utilized. FDA has the ability to grant complete waivers, partial waivers, or deferrals for compliance with PREA. PREA requirements may be waived for applications for approval of drug candidates intended to treat, mitigate, prevent, diagnose or cure diseases and other conditions that do not occur in pediatric populations. Generally, PREA does not apply for drug candidates which have obtained an orphan designation, unless otherwise regulated by the FDA. Despite this, separate PREA compliance or waivers may still be required for each product indication. Although noncompliance with PREA will generally not be considered for withdrawal of an approval it may be considered by the FDA as the sole basis for enforcement action such as injunction or seizure as non-compliance and may render the drug misbranded.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

### ***Marketing Exclusivity***

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity ("NCE"). A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. The FDCA also permits patent term restoration of up to five years as compensation for a patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. During the NCE exclusivity period, the FDA may not approve, or even accept for review, an abbreviated new drug application ("ANDA") or an NDA submitted under Section 505(b)(2) (505(b)(2) NDA), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which we refer to as the Orange Book, with the FDA by the innovator NDA holder. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book.



These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. Any competitor who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make patent certifications to the FDA that: (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) the patent has expired; (3) the date on which the patent has expired and approval will not be sought until after the patent expiration; or (4) the patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. If the drug has NCE exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires 7 1/2 years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. The indications the Company is currently pursuing for its product candidates will not be eligible for pediatric exclusivity because they are age-related degenerative diseases and disorders that do not occur in the pediatric population. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances/

### ***Other Healthcare Laws***

Pharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, anti-self-referral, false claims, transparency, including the federal Physician Payments Sunshine Act, consumer fraud, pricing reporting, data privacy, data protection, and security laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the United States *Health Insurance Portability and Accountability Act of 1996* (HIPAA), thus complicating compliance efforts. For example, California recently enacted the *California Consumer Privacy Act of 2018* ("CCPA"), which creates individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. Under the CCPA the California Attorney General may bring enforcement actions for violations of the CCPA. Further, California voters approved a new privacy law, the *California Privacy Rights Act* ("CPRA"), in the November 3, 2020 election which amends and expands the CCPA. The CPRA became fully effective on January 1, 2023, and significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency, the California Privacy Protection Agency, that is vested with authority to implement and enforce the CCPA and the CPRA. New legislation proposed or enacted in various other states will continue to shape the data privacy environment nationally.

The risk of our being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Actual or alleged violation of any such laws or regulations may lead to investigations and other claims and proceedings by regulatory authorities and in certain cases, private actors, and violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

The United States Federal Office of Inspector General ("OIG"), continues to make modifications to the existing Federal Anti-Kickback Statute ("AKS") safe harbors which may increase liability and risk as well as adversely impact sales relationships. On November 20, 2020, OIG issued the final rule for Safe Harbors under the AKS. This new final rule creates additional safe harbors including ones pertaining to patient incentives. OIG is able to modify safe harbors as well as regulatory compliance requirements which could impact our business adversely. The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

### ***Coverage and Reimbursement***

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific details, information on cost-effectiveness, and clinical support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

At the state level, there are also new laws and ongoing ballot initiatives that create additional pressure on drug pricing and may affect how pharmaceutical products are covered and reimbursed. A number of states have adopted or are considering various pricing actions, such as those requiring pharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on certain products. Existing and proposed state pricing laws have added complexity to the pricing of pharmaceutical drug products.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

### ***Healthcare Reform***

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; it required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; it implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; it expanded the eligibility criteria for Medicaid programs; it created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and it established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services (“CMS”), to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since January 2017, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. For example, in 2017, Congress enacted the Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, a process that is commonly referred to as

the “individual mandate.” In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case and held oral arguments in November 2020. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. There may be other efforts to challenge, repeal, or replace the ACA. If successful, it may potentially impact our business in the future.

President Joseph R. Biden, Jr. signed the Executive Order on Strengthening Medicaid and stating his administration’s intentions to reverse the actions of his predecessor and strengthen the ACA. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they are consistent with ensuring both coverage under the ACA and if they make high-quality healthcare affordable and accessible to Americans. We are unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact our profitability. President Biden intends, as his predecessor did, to take action against drug prices which are considered “high.” The most likely time to address this would be in the reauthorization of PDUFA in 2022 as part of a package bill. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government, and we expect to see legislation focusing on this in the coming year. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. The Prescription Drug Pricing Reduction Act, or PDPRA, which was introduced in Congress in 2019, and again in 2020, proposed to, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and proposes a number of changes to how drugs are reimbursed in Medicare Part B. A similar drug pricing bill, the Elijah E. Cummings Lower Drug Costs Now Act proposes to enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped based on an international index), requires manufacturers to offer these negotiated prices to other payers, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. This Act passed in the House of Representatives when it was introduced in

2019, and it has been introduced again in the 2021 term. We cannot predict whether any proposed legislation will become law and the effect of these possible changes on our business cannot be predicted at this time.

### **Legal Proceedings**

From time to time, we are involved in various legal proceedings arising from the normal course of business activities. We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

### **Competition**

We face substantial competition from multiple sources, including large and specialty biotechnology and pharmaceutical companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge.

In addition to the current standard of care treatments for patients with neurodegenerative diseases, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess technologies and product candidates in the central nervous system field.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, commercialization, and marketing than we do. Mergers and acquisition activity in the biopharmaceutical sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of our programs are likely to be product safety, efficacy, convenience and treatment cost.

### **Reorganizations**

On March 18, 2021, the Company completed its Qualifying Transaction. As a result of the Qualifying Transaction, Alpha Canada became the Company's wholly-owned subsidiary. For more information regarding the Qualifying Transaction, please see the Filing Statement available on the Company's SEDAR profile at [www.sedar.com](http://www.sedar.com).

## **RISK FACTORS**

Investing in our Common Shares involves a high degree of risk. Prospective investors should carefully consider the risks described in Schedule “B” *Risk Factors* attached hereto, together with all of the other information included or referred to in this AIF, before purchasing securities of the Company. The risks set out in Schedule “B” are not the only risks we face. Additional risks and uncertainties not presently known to us or not presently deemed material by us might also impair our operations and performance. If any of these risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our Common Shares could decline and investors in our Common Shares could lose all or part of their investment.

## **DIVIDENDS AND DISTRIBUTIONS**

The Company has paid no dividends since its inception. At the present time, the Company intends to retain any earnings to fund working capital and grow the business of the Company. The payment of dividends in the future will depend on the earnings and financial condition of the Company and on such other facts as the Board may consider appropriate. There are no plans to pay dividends in the foreseeable future.

## **CAPITAL STRUCTURE**

The authorized capital of the Company consists of an unlimited number of Common Shares without par value, an unlimited number of Class A restricted voting shares without par value (“**Restricted Shares**”) and an unlimited number of Class B Preferred Series A shares without par value (“**Preferred Shares**”). As at June 26, 2023, there were 87,950,664 Common Shares issued and outstanding, 7,000,000 Restricted Shares issued and outstanding and 7,916,380 Preferred Shares issued and outstanding. There are options outstanding to purchase up to 21,086,071 Common Shares at exercise prices ranging from US\$0.40 to US\$0.80 and C\$0.22 to C\$0.71. There are warrants outstanding to purchase up to 37,436,200 Common Shares at exercise prices ranging at US\$0.40 and from C\$0.39 to C\$1.50. There are performance shares outstanding to purchase up to 8,471,057 Common Shares at an exercise price of \$0.01.

### *Common Shares*

The holders of the Common Shares are entitled to notice of, to attend, and to vote at all meetings of the Company’s shareholders. The holders of the Common Shares are entitled to receive dividends if, as and when declared by the directors, and rank *pari passu* with one another in any distribution of property or assets upon the liquidation, winding-up or other dissolution of the Company.

The Common Shares carry no pre-emptive rights, conversion or exchange rights, retraction, sinking fund or purchase fund provisions. There are no provisions requiring the holders the Common Shares of the Company to contribute additional capital and no restrictions on the issuance of additional securities by the Company. There are no restrictions on the repurchase or redemption of shares by the Company except as otherwise set out herein and to the extent that any such repurchase or redemption would render the Company insolvent pursuant to the BCBCA.

### *Restricted Shares*

The Company’s Restricted Shares were issued to certain holders of common shares of Alpha Canada who are resident in the United States in connection with the Company’s Qualifying Transaction to allow the Company to maintain its status as a Foreign Private Issuer. As of January 1, 2023, the Company no longer qualifies as a Foreign Private Issuer and the Company expects that the Restricted Shares will be converted

to Common Shares. The conversion of the Restricted Shares to Common Shares may be effected by resolution of the Board, which the Company currently anticipates will be completed in 2023. The Restricted Shares differ from the Common Shares in that they do not entitle the holder to exercise voting rights in respect of the election of directors of the Company.

The Restricted Shares include the following restrictions, conditions and limitations:

- (1) The holders of the Restricted Shares are entitled to receive notice of and attend all meetings of the shareholders of the Company and are entitled to vote at meetings of the holders of Common Shares, except those holders of Restricted Shares are not entitled to vote for the election or removal of directors of the Company.
- (2) The holders of Restricted Shares are entitled to receive dividends as and when declared by the Board of the Company, provided that no dividend may be declared or paid in respect of Restricted Shares unless concurrently therewith the same dividend is declared or paid on the Common Shares.
- (3) The holders of Restricted Shares are entitled, in the event of any liquidation, dissolution or winding-up, whether voluntary or involuntary, or any other distribution of the assets of the Company among its shareholders for the purpose of winding up its affairs, to share rateably, together with the holders of the Common Shares, in such assets of the Company as are available for distribution.
- (4) Restricted Shares may only be transferred pursuant to an offer to purchase Restricted Shares made to all of the holders of the Restricted Shares.
- (5) If an offer is made to purchase all or substantially all of the Common Shares, each Restricted Share shall be deemed converted into one Common Share concurrent with closing of the offer.

Each Restricted Share will be convertible into one Common Share at the option of the holder of the Restricted Share at any time: (i) if the Company enters into a binding agreement that would result in a change of control; or (ii) if a meeting of shareholders is called to elect directors who are not nominees of the Company or management of the Company or if a meeting of shareholders is called at which a contested election of directors will be considered.

### *Preferred Shares*

The Preferred Shares were issued to certain founders of Alpha Canada in connection with the Company's Qualifying Transaction.

The Preferred Shares include the following restrictions, conditions and limitations:

- (1) The Preferred Shares have a deemed issue price of \$0.25 ("**Deemed Issue Price**").
- (2) The holders of the Preferred Shares will be entitled to receive notice of and attend all meetings of the shareholders of the Company and will be entitled to vote at meetings of the holders of Common Shares. The holders of Preferred Shares will vote together with holders of Common Shares and Restricted Shares as a single class.



- (3) The holders of Preferred Shares will be entitled to receive dividends as and when declared by the Board. The Preferred Shares rank in priority to the Common Shares and Restricted Shares for payment of dividends. Dividends on the Preferred Shares are non-cumulative. If the holders of the Preferred Shares receive dividends in an aggregate amount equal to or greater than the Deemed Issue Price, the Preferred Shares shall be automatically converted to Common Shares.
- (4) In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Preferred Shares shall be entitled to receive out of the assets and funds of the Company, prior and in preference to any distribution of any of the assets or funds of the Company to the holders of the Common Shares and Restricted Shares, an amount per Preferred Share equal to two times the Deemed Issue Price of the Preferred Shares (as appropriately adjusted for any stock dividends, combinations or splits) plus all accrued or declared but unpaid dividends on such Preferred Shares (the “**Liquidation Preference**”). After payment in full of the Liquidation Preference has been made to the holders of the Preferred Shares, all remaining assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of the Preferred Shares, Common Shares and Restricted Shares. Upon payment of the Liquidation Preference, each Preferred Share will convert into one Common Share.
- (5) Each Preferred Shares shall, at the option of the holder, be convertible into Common Shares at the rate of one Common Share for each Preferred Share. All of the Preferred Shares will be automatically converted to Common Shares if any of the following events occur:
  - (a) upon the completion of an initial public offering, or a reverse take-over with a qualifying secondary offering, pursuant to which the Common Shares are listed for trading on the New York Stock Exchange, NYSE Amex, the NASDAQ National Market or SmallCap Quotation System or a successor to any of the foregoing, raising at least US\$40 million, and a price per share which values the Company at US\$160 million or more, prior to listing;
  - (b) A third party makes a bona fide offer to acquire 100% of the Common Shares, or execute a merger or amalgamation in which effective control of the Company is transferred, and such offer has been approved by the Board and its shareholders, such that shareholders receive proceeds from the transaction of at least US\$160 million in the form of shares or cash or a combination of both;
  - (c) A third party makes a bona fide offer to acquire all or substantially all of the Company’s assets, for sale proceeds of at least US\$180 million and such offer has been approved by the Board and its shareholders, and provided that the shareholders on closing receive proceeds from the transaction by way of dividend and return of capital or otherwise of at least US\$160 million;  
or
  - (d) A third party makes a bona fide offer to acquire certain specific Company asset(s), for sale proceeds of at least US\$180 million, and provided that the provision of subsection (c) is not triggered, and such offer has been approved by the Board and provided that the shareholders on closing receive proceeds from the transaction by way of dividend, return of capital or otherwise of at least US\$160 million,

If the Preferred Shares are subject to automatic conversion as a result of the occurrence of one of the above events, prior to such conversion they shall be entitled to receive a dividend per Preferred Share equal to the Deemed Issue Price.

*Warrants*

As at June 26, 2023, the Company had 37,436,200 warrants to purchase Common Shares of the Company outstanding as follows:

<b>Date of Issuance</b>	<b>Number Issued</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
March 15, 2023	7,277,069	\$0.39	March 15, 2028
February 16, 2023	16,795,221	\$0.39	February 16, 2028
October 1, 2021	9,602,500	\$1.75	October 1, 2023
October 1, 2021	659,627	\$1.50	October 1, 2023
March 18, 2021	40,000	US\$0.40	July 5, 2023
March 18, 2021	3,061,783	US\$0.40	August 30, 2024

*Stock Options*

As at June 26, 2023, the Company had 21,086,071 stock options to purchase Common Shares outstanding as follows:

<b>Date of Issuance</b>	<b>Number Issued</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
June 8, 2023	16,190,000	\$0.22	June 8, 2033
January 18, 2023	450,000	\$0.28	May 31, 2032
January 18, 2023	450,000	\$0.28	April 11, 2032
January 18, 2023	215,000	\$0.28	February 14, 2032
January 18, 2023	940,000	\$0.28	December 20, 2031
January 18, 2023	2,600,000	\$0.28	August 3, 2031
August 16, 2021	131,250	US\$0.80	August 16, 2031
March 18, 2021	39,154	US\$0.40	July 22, 2030
March 18, 2021	39,154	US\$0.40	June 1, 2029
March 18, 2021	31,513	\$0.714	September 21, 2023

*Performance Shares*

As at June 26, 2023, the Company had 8,471,057 performance shares to purchase Common Shares outstanding as follows:

<b>Date of Issuance</b>	<b>Number Issued</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
March 18, 2021	2,180,000	US\$0.01	May 31, 2029
March 18, 2021	3,050,000	US\$0.01	August 31, 2028
March 18, 2021	691,057	US\$0.01	December 31, 2027
March 18, 2021	900,000	US\$0.001	February 1, 2026
March 18, 2021	1,650,000	US\$0.01	December 31, 2024

## MARKET FOR SECURITIES

### Trading Price and Volume

The Common Shares currently trade on the CSE under the symbol “ACOG” and on the OTCQB under the symbol “ACOGF”. Prior to May 1, 2023, the Common Shares were traded on the TSX-V under the symbol “ACOG”. The following table shows the high and low trading prices and total trading volume of the Common Shares on the TSX-V on a monthly basis for the financial year ended December 31, 2022:

Month	High	Low	Volume
December 2022	\$0.38	\$0.24	265,938
November 2022	\$0.55	\$0.34	193,103
October 2022	\$0.45	\$0.27	265,628
September 2022	\$0.68	\$0.43	106,263
August 2022	\$0.79	\$0.57	100,183
July 2022	\$0.85	\$0.50	136,253
June 2022	\$0.68	\$0.49	1,351,455
May 2022	\$0.97	\$0.62	461,818
April 2022	\$1.03	\$0.78	336,662
March 2022	\$1.19	\$0.90	606,056
February 2022	\$1.10	\$0.88	168,145
January 2022	\$1.15	\$0.90	285,031

The Listed Warrants trade on the TSX-V under the symbol “ACOG.WT”. The following table shows the high and low trading prices and total trading volume of the Listed Warrants on the TSX-V on a monthly basis for the financial year ended December 31, 2022:

Month	High	Low	Volume
December 2022	\$0.005	\$0.005	0
November 2022	\$0.005	\$0.005	0
October 2022	\$0.05	\$0.005	19,000
September 2022	\$0.05	\$0.05	0
August 2022	\$0.06	\$0.05	3,000
July 2022	\$0.06	\$0.06	0
June 2022	\$0.15	\$0.06	5,500
May 2022	\$0.30	\$0.14	29,000
April 2022	\$0.30	\$0.25	7,000
March 2022	\$0.40	\$0.20	434,600
February 2022	\$0.30	\$0.20	21,500
January 2022	\$0.30	0.25	12,500

### Prior Sales

During the most recently completed financial year the Company did not issue any securities are outstanding, but not listed or quoted on a marketplace.

**ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL  
RESTRICTIONS ON TRANSFER**

The following table outlines the number of securities held, to the knowledge of the Company, in escrow or that are subject to a contractual restriction on transfer for the Company's most recently completed financial year.

Designation of Class	Number of securities held in escrow or that are subject to a contractual restriction on transfer	Percentage of Class
Common Shares	19,754,347 <sup>(1)(2)(3)</sup>	32.37%
Restricted Shares	3,116,518 <sup>(4)</sup>	44.52%
Preferred Shares	5,099,866 <sup>(5)</sup>	64.42%
Performance Shares	6,546,243 <sup>(6)</sup>	68.76%
Warrants	740,649 <sup>(4)</sup>	4.63%

**Notes:**

- (1) 12,804,553 Common Shares are subject to the Escrow Agreement.
- (2) 279,834 Common Shares are subject to the CPC Escrow Agreement.
- (3) 6,669,960 Common Shares are subject to the TSX-V seed share resale restrictions (the "Seed Share Resale Restrictions").
- (4) These securities are subject to the Escrow Agreement.
- (5) 4,304,986 Preferred Shares are subject to the Escrow Agreement. 794,880 Preferred Shares are subject to the Seed Share Resale Restrictions.
- (6) 6,343,743 performance shares are subject to the Escrow Agreement. 202,500 performance shares are subject to the Seed Share Resale Restrictions.

**Escrow Agreement**

Pursuant to the terms of the Escrow Agreement, the securities are released in accordance with the TSX-V Tier 2 surplus escrow schedule as follows:

Release Dates	Percentage of Total Escrowed Securities to be Released	Total Number of Escrowed Securities to be Released
March 29, 2021	5%	1,972,172
September 29, 2021	5%	1,972,172
March 29, 2022	10%	3,944,345
September 29, 2022	10%	3,944,345
March 29, 2023	15%	5,916,518
September 29, 2023	15%	5,916,518
March 29, 2024	40%	15,777,389

**CPC Escrow Agreement**

Pursuant to the terms of the CPC Escrow Agreement, the 621,850 Common Shares initially subject to the CPC Escrow Agreement are released in accordance with the TSX-V Tier 2 value escrow schedule as follows:

Release Dates	Percentage of Total Escrowed Securities to be Released	Total Number of Escrowed Securities to be Released
March 29, 2021	10%	62,185

Release Dates	Percentage of Total Escrowed Securities to be Released	Total Number of Escrowed Securities to be Released
September 29, 2021	15%	93,277
March 29, 2022	15%	93,277
September 29, 2022	15%	93,277
March 29, 2023	15%	93,277
September 29, 2023	15%	93,278
March 29, 2024	15%	93,279

### TSX-V Seed Share Resale Restrictions

There were initially an aggregate of 15,409,612 Common Shares, 1,766,400 Preferred Shares and 500,000 performance shares held by non-principals of the Company which were subject to the TSX-V seed share resale restrictions. The resale restrictions are removed from these securities in accordance with the TSX-V Tier 2 value escrow schedule as follows:

Release Dates	Percentage of Securities to be Released	Total Number of Securities to be Released
March 29, 2021	10%	1,767,601
September 29, 2021	15%	2,651,401
March 29, 2022	15%	2,651,401
September 29, 2022	15%	2,651,401
March 29, 2023	15%	2,651,401
September 29, 2023	15%	2,651,401
March 29, 2024	15%	2,651,406

## DIRECTORS AND OFFICERS

### Name, Occupation and Security Holding

The following table sets out the names of the current directors and executive officers of the Company, the provinces or states and countries of their residence, their positions with the Company, their principal occupations within the five preceding years, the periods during which each director has served as a director of the Company and the number of Common Shares and percentage of the issued Common Shares beneficially owned, directly or indirectly, or subject to control or direction by that person.

The term of each of the current directors of the Company will expire at the next annual general meeting unless their office is earlier vacated in accordance with the Articles of the Company, or they become disqualified to act as a director.

Name, Position and Municipality of Residence	Principal Occupation for the Past Five Years <sup>(1)</sup>	Director/ Executive Officer Since	Number and Percentage of Voting Securities Beneficially Owned or Controlled <sup>(2)</sup>
<b>Michael McFadden</b> Texas, United States <i>CEO and Director</i>	Mr. McFadden's principal occupation is acting as the CEO of the Company. Prior to this he was Chief Commercial Officer (CCO) for MPower Health.	CEO since April 12, 2021  Director since March 28, 2022	220,166 Common Shares <1%

Name, Position and Municipality of Residence	Principal Occupation for the Past Five Years <sup>(1)</sup>	Director/ Executive Officer Since	Number and Percentage of Voting Securities Beneficially Owned or Controlled <sup>(2)</sup>
<b>Don Kalkofen</b> Texas, United States <i>CFO</i>	From 2018 to 2019 Mr. Kalkofen was acting as the CFO a financial services and global SAAS company. From 2019 to 2022 Mr. Kalkofen served as CFO of Protagonist Therapeutics Inc. (NASDAQ: PTGX), a publicly-traded biopharmaceutical company.	April 11, 2022	10,000 Common Shares <1%
<b>Lauren D'Angelo</b> California, United States <i>Chief Commercial Officer</i>	Ms. D'Angelo's principal occupation is acting as the CCO of the Company. Previously, Ms. D'Angelo served as Vice President, Marketing and Commercial Strategy at Urovant Sciences.	May 4, 2021	Nil
<b>Kenneth Cawkell<sup>(3)</sup></b> New Westminster, British Columbia <i>Corporate Secretary and Director</i>	Mr. Cawkell co-founded Cawkell Brodie LLP, a Vancouver based law firm, where he acted as managing partner from 1987 to 2022. Mr. Cawkell is a founder and CEO of Neurodyn Life Sciences Inc., a private biotech company focused on developing natural based products to promote healthy ageing. Mr. Cawkell is also a founder of Alpha Cognition Inc.	March 18, 2021	5,361,899 Common Shares 6.1%  2,000,000 Preferred Shares 25.3%
<b>Len Mertz<sup>(3)(5)</sup></b> Texas, United States <i>Chairman and Director</i>	Mr. Mertz is Chairman of Shannon West Texas Memorial Hospital and a cofounder of Mayne & Mertz, Inc. an oil & gas exploration company. Mr. Mertz is also on the board of the First National Bank of Mertz.	March 18, 2021	5,956,423 Common Shares 6.8%  2,143,774 Restricted Shares 30.6%  3,266,780 Preferred Shares 41.3%
<b>John Havens<sup>(4)(5)</sup></b> Texas, United States <i>Director</i>	Mr. Havens is the President of Seismic Exchange, Inc. Mr. Havens also serves as Vice Chairman/Board Member of the Houston Astros.	March 18, 2021	5,708,482 Common Shares 6.5%  1,322,506 Restricted Shares 18.9%

Name, Position and Municipality of Residence	Principal Occupation for the Past Five Years <sup>(1)</sup>	Director/ Executive Officer Since	Number and Percentage of Voting Securities Beneficially Owned or Controlled <sup>(2)</sup>
<b>Phillip Mertz</b> <sup>(4)(5)</sup> Virginia, United States <i>Director</i>	Mr. Mertz is the CEO of Subtle Technology, a neurotechnology company, and is a partner in Mertz Holdings. Mr. Mertz is also a cofounder of Secure Open Solutions, a cybersecurity and compliance management company. Previously Mr. Mertz led business development for CNG Energy, and worked as a management consultant with Touchstone Consulting Group.	March 18, 2021	269,910 Common Shares <1%  985,912 Restricted Shares 14.1%  883,200 Preferred Shares 11.2%
<b>Rajeev ‘Rob’ Bakshi</b> <sup>(3)(5)</sup> White Rock, British Columbia <i>Director</i>	Mr. Bakshi has been the CEO of Active Witness Corp. from 2018 to present. In 2013, Mr. Bakshi was appointed CEO of Apivio Systems Inc.	March 18, 2021	296,079 Common Shares <1%

**Notes:**

- (1) The information as to principal occupation and business or employment, has been provided by the directors and officers.
- (2) The information as to securities of the Company beneficially owned or controlled has been provided by the directors and officers.
- (3) Member of Audit Committee.
- (4) Member of the Compensation Committee.
- (5) Member of the Governance Committee.

**Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

Other than as disclosed below, to the knowledge of the Company, no director or executive officer of the Company, or a personal holding company of such person is, as at the date of this AIF, or has been, within 10 years before the date of this AIF, a director, chief executive officer (“CEO”) or chief financial officer (“CFO”) of any company that:

- (a) was subject to a cease trade or similar order to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued while the director or executive officer was acting in the capacity as a director, CEO or CFO of such company; or
- (b) was subject to a cease trade or similar order to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued after the director or executive officer ceased to be a director, CEO or CFO but which resulted from an event that occurred while the director or executive officer was acting in the capacity as director, CEO or CFO of such company.

Mr. Cawkell is a director of Centurion Minerals Ltd. (“**Centurion**”) and Mr. Wright is a director and the CFO of Centurion. Centurion was subject to a cease trade order (the “**CTO**”) issued by the British Columbia Securities Commission on December 5, 2017, for failure to file its audited annual financial statements for the year ended July 31, 2017. Subsequently, Centurion dismissed its auditor on February 13, 2018, as its board of directors lost confidence in the former auditors’ ability to complete the audit in a timely fashion, if at all. Centurion engaged a new auditor to complete the audit and filed its audited annual financials for the year ended July 31, 2017 on March 1, 2018 and its first quarter on March 13, 2018. The CTO was revoked on May 3, 2018.

To the knowledge of the Company, no director or executive officer of the Company, or a shareholder holding a sufficient number of securities to affect materially the control of the Company, or a personal holding company of such person:

- (a) is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets;
- (b) has, within the 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director or executive officer;
- (c) has been subject to any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- (d) has been subject to any penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

### **Conflicts of Interest**

The Company’s directors and officers may serve as directors or officers of other companies, including the TBI Company, or have significant shareholdings in other companies and, to the extent that such other companies may participate in ventures in which the Company may participate, the directors or officers of the Company may have a conflict of interest in negotiating and concluding terms respecting the extent of such participation. In the event that such a conflict of interest arises at a meeting of the Company’s directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. The directors of the Company are required to act honestly, in good faith and in the best interests of the Company.

The directors and officers of the Company are aware of the existence of laws governing the accountability of directors and officers for corporate opportunity and requiring disclosures by the directors and officers of conflicts of interest and the Company will rely upon such laws in respect of any directors’ and officers’ conflicts of interest or in respect of any breaches of duty by any of its directors and officers. All such conflicts will be disclosed by such directors or officers in accordance with the BCBCA and will govern themselves in respect thereof to the best of their ability in accordance with the obligations imposed upon them by law.



To the best of the Company's knowledge, and other than as disclosed above and elsewhere in this AIF, there are no known existing or potential conflicts of interest among the Company, its subsidiaries, directors and officers or other members of management of the Company or its subsidiaries as a result of their outside business interests.

### **Audit Committee Information**

Pursuant to the provisions of the BCBCA and NI 52-110 of the Canadian Securities Administrators, the Company is required to have an Audit Committee and to disclose in its AIF certain information concerning the constitution of its Audit Committee and its relationship with the Company's independent auditor. The general function of the Audit Committee is to review the overall audit plan and the Company's system of internal controls, to review the results of the external audit, and to resolve any potential dispute with the Company's auditor.

#### Audit Committee Charter

A copy of the charter of the Audit Committee is attached to this AIF as Schedule "A".

#### Composition of the Audit Committee

The Company's current Audit Committee consists of Kenneth Cawkell (independent), Len Mertz (not independent), and Rajeev 'Rob' Bakshi (independent).

NI 52-110 provides that a member of an audit committee is "independent" if the member has no direct or indirect material relationship with the Company, that could, in the view of the Board, reasonably interfere with the exercise of the member's independent judgment.

NI 52-110 provides that an individual is "financially literate" if he or she has the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements. All of the members of the Audit Committee are "financially literate" as that term is defined. The following sets out the Audit Committee members' education and experience that is relevant to the performance of his responsibilities as an audit committee member.

#### Relevant Education and Experience

*Kenneth Cawkell* – Mr. Cawkell is a retired, non-practicing member of the British Columbia Bar Association, and, in 1987, he co-founded the law firm Cawkell Brodie LLP, where he acted as managing partner until 2022. Mr. Cawkell has been involved for over 25 years in the biotech industry as both a professional advisor, investor and a founding principal. Mr. Cawkell has gained extensive strategic and development experience as a result of his long-term association with numerous public and private biotechnology companies and he has been involved in several successful exits. He is a past member of the National Research Council of Canada IMB/INH Advisory Board and a number of biotech industry associations. Mr. Cawkell received a B.A. and an LL.B from the University of Alberta.

*Len Mertz* – As a Partner of Mertz Holdings, Mr. Mertz is an experienced board member with investments in several early-stage healthcare and biotech companies including Triumvira Immunologics, and Photodynamic. In addition, he is also Chairman of Shannon West Texas Memorial Hospital, a CMS rated 5-star hospital with annual revenues in excess of \$1 billion. Mr. Mertz is a cofounder of Mayne & Mertz, Inc. an oil & gas exploration company and is on the board of the First National Bank of Mertz. He began his career as a certified public accountant obtaining his BBA in Finance and his Masters in Professional Accounting from the University of Texas at Austin.

*Rajeev ‘Rob’ Bakshi* Mr. Bakshi was the co-founder of technology company, Silent Witness Enterprises Ltd., which was listed on the TSX and NASDAQ. He oversaw the company’s growth strategy before being sold to Honeywell for approximately \$90 million in 2003. Since then, he has been involved with industrial land development, building a Convention Centre in Calgary and other strategic investments. In 2009, Mr. Bakshi began working with a South Korean company to establish Apivio Systems Inc. He led the strategy to turn the business into a Canadian company, putting together an independent board of directors, financing, and corporate governance in his capacity of Executive Chairman. In 2013, he was appointed CEO and was responsible for taking the company public. Apivio Systems Inc. was acquired by Nuri Telecom Company in an all-cash transaction in the spring of 2017. Mr. Bakshi received a Bachelor’s degree in computer science from Simon Fraser University.

#### Reliance on Certain Exemptions

Since the effective date of NI 52-110, the Company has not relied on the exemptions contained in sections 2.4 (De Minimis Non-Audit Services), subsection 6.1.1(4) (Circumstance Affecting the Business or Operations of the Venture Issuer), subsection 6.1.1(5) (Events Outside Control of Member), subsection 6.1.1(6) (Death, Incapacity or Resignation), or under Part 8 (Exemption) of NI 52-110.

#### Audit Committee Oversight

Since the commencement of the Company’s most recently completed financial year, the Audit Committee of the Company has not made any recommendations to nominate or compensate an external auditor that were not adopted by the Board.

#### Pre-Approval Policies and Procedures

The Audit Committee has not adopted any specific policies and procedures for the engagement of non-audit services.

#### External Auditor Service Fees

The aggregate fees billed to the Company for the last two (2) fiscal years noted below by Manning Elliott LLP, the Company’s auditor, are as follows:

<b>Financial Year Ending</b>	<b>Audit Fees</b>	<b>Audit Related Fees</b>	<b>Tax Fees</b>	<b>All Other Fees</b>
December 31, 2022	\$110,000	\$124,975	Nil	Nil
December 31, 2021	\$120,000	\$37,200	Nil	Nil

## LEGAL PROCEEDINGS AND REGULATORY ACTIONS

The Company is not aware of any legal proceedings to which the Company is or was a party, or to which the Company's property is or was subject, either during the financial year ended December 31, 2022, or as of the date hereof, nor is the Company aware that any such proceedings are contemplated.

## INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as disclosed in this AIF, no informed person (a director, officer or holder of 10% or more Common Shares) or any associate or affiliate of any informed person had any interest, direct or indirect, in any transaction which has materially affected or is reasonably expected to materially affect the Company or any of its subsidiaries, within the three most recently completed financial years or during the current financial year as at the date of this AIF.

## TRANSFER AGENT AND REGISTRAR

The Company's Registrar and Transfer Agent for the Common Shares is Computershare Investor Services Inc at its principal offices at 510 Burrard Street, 3<sup>rd</sup> Floor, Vancouver, British Columbia, V6C 3B9.

The Company's Registrar and Transfer Agent for the Warrants is Computershare Trust Company of Canada of 510 Burrard Street, 3<sup>rd</sup> Floor, Vancouver, British Columbia, V6C 3B9.

## MATERIAL CONTRACTS

The following is a description of each material contract entered into by the Company since the beginning of the last financial year ended December 31, 2022, or before the last financial year, if such material contract is still in effect:

1. ALPHA-1062 Agreement dated March 23, 2015, as amended effective April 1, 2015. See "*Information Concerning the Target Company – General Development of the Business – History*" in the Filing Statement.
2. ALPHA-1062 Royalty Agreement dated January 1, 2016. See "*Information Concerning the Target Company – General Development of the Business – History*" in the Filing Statement.
3. CPC Escrow Agreement dated August 30, 2018, between the Company, Computershare, and certain and certain shareholders of the Company.
4. ALPHA-0602 Agreement dated January 1, 2020, as amended November 4, 2020. See "*Information Concerning the Target Company – General Development of the Business – History*" in the Filing Statement.
5. ALPHA-0602 Royalty Agreement dated November 3, 2020. See "*Information Concerning the Target Company – General Development of the Business – History*" in the Filing Statement.
6. Escrow Agreement dated March 18, 2021 between the Company, Computershare, and certain shareholders of the Company.
7. Warrant Indenture dated October 1, 2021 between the Company and Computershare Trust Company of Canada in connection with the warrants issued pursuant to the bought deal financing of units that closed on October 1, 2021 for aggregate gross proceeds of approximately \$14.4 million.

8. A Second Amended License Agreement dated March 1, 2023, between the Company and Neurodyn Life Sciences Inc. for the exclusive world-wide license ALPHA 1062 technology.

### **INTEREST OF EXPERTS**

Manning Elliott LLP, Chartered Professional Accountants, is the independent registered public accounting firm of the Company and is independent within the meaning of the Code of Professional Conduct of the Chartered Professional Accountants of British Columbia.

### **ADDITIONAL INFORMATION**

Additional information relating to the Company may be found on SEDAR at [www.sedar.com](http://www.sedar.com).

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans, is contained in the Company's information circular dated May 15, 2023.

Additional financial information is provided in the Company's audited financial statements and Annual MD&A for the year ended December 31, 2022.

Copies of the Company's financial statements and Annual MD&A may be obtained upon request from the Company's head office by mail to 301 – 1228 Hamilton Street, Vancouver, British Columbia, V6B 6L2, or may be viewed on SEDAR ([www.sedar.com](http://www.sedar.com)) under "Company Profiles – Alpha Cognition Inc."

## **Schedule “A”**

### **Audit Committee Charter of Alpha Cognition Inc. (the “Company”)**

#### **1. Purposes and Responsibilities**

The Audit Committee (the “Committee”) shall assist the Board in fulfilling its responsibility for oversight of the Company’s financial accounting and reporting, the system of internal controls established by management, and the adequacy of internal and independent auditing relative to these activities.

#### **2. Authority to Retain Experts**

The Committee shall have the authority to retain outside counsel or other experts as necessary to assist the Committee in fulfilling its responsibilities. The Company will provide adequate funding, as determined by the Committee, to pay such outside counsel or other experts and cover all other costs of the Committee in fulfilling its responsibilities hereunder.

#### **3. Reporting**

The Audit Committee shall report to the Board.

#### **4. Appointment and Composition**

The Committee and its Chair shall be appointed by the Board. The Chair shall be a member of the Committee.

The Committee shall consist of at least three directors, a majority of whom must not be executive officers, employees or control persons of the Company or of an affiliate of the Company. If the Company lists its common shares on the Nasdaq Stock Market, then the Committee shall consist of at least three directors, all of whom are independent (as that term is used in National Instrument 52-110, Rule 10A-3 of the United States Securities Exchange Act of 1934, as amended (the “Exchange Act”), the rules and regulations of the United States Securities and Exchange Commission and the listing rules of the Nasdaq Stock Market), that is, who are independent of management and are free from any interest and any business or other relationship which could, or might reasonably be perceived to, materially interfere with their ability to act with a view to the best interests of the Company, other than interests and relationships arising from shareholding.

Each of the members of the Committee shall have a working familiarity with basic finance and accounting practices, and shall have experience with reviewing and approving public company financial statements, either as part of management or as a member of a public company’s audit committee. Each member of the members of the Committee must be able to read and understand fundamental financial statements, including the Company’s balance sheet, income statement and cash flow statement.

At least one member of the Committee shall have accounting or related financial management expertise sufficient to be considered a “financial expert” under Item 407(d)(5) of Regulation S-K under the Exchange Act and “financially sophisticated” under the listing standards of the Nasdaq Stock Market.

#### **5. Duties**

- a) The Committee shall:
- b) Provide for an open avenue of communications between the independent auditors, management and the Board and, at least once annually, meet with the independent auditors independently of management.

- c) Review the qualifications and evaluate the performance of the independent auditors and be directly responsible for the compensation, retention and oversight of the independent auditors. The independent auditors shall be ultimately accountable to the Board and the Committee, as representatives of the shareholders.
- d) Inquire as to the independence of the external auditors and obtain, at least annually, a formal written statement delineating all relationships between the independent auditors and the Company as contemplated by Independence Standards Board Standard No. 1 – Independence Discussions with Audit Committees and under any applicable rules of the Public Company Accounting Oversight Board and discuss with the auditors any relationships that may impact the auditor’s independence.
- e) Review and approve the independent auditors’ annual engagement letter.
- f) Review with the independent auditors (1) the proposed scope of their examination with emphasis on accounting and financial areas where the Committee, the independent auditors or management believe special attention should be directed, (2) the results of their audit, including their letter of recommendations for management (3) their evaluation of the adequacy of the Company’s system of internal controls, (4) significant areas of disagreement, if any, with management (5) cooperation received from management in the conduct of the audit and (6) significant accounting, reporting, regulatory or industry developments affecting the Company.
- g) Discuss with management and the independent auditors any issues regarding significant business risks or exposures and assess the steps management has taken to minimize such risk.
- h) Review with management and the independent auditors the Company’s unaudited quarterly financial statements and the Company’s audited annual financial statements and make a recommendation to the Board as to approval thereof.
- i) In reviewing the quarterly and annual financial statements, include a review of estimates, reserves, accruals, write downs, judgmental areas, audit adjustments, difficulties encountered in performing any audit, and such other review as may be appropriate.
- j) Review and satisfy itself on behalf of the Board with respect to the Company’s internal control over financial reporting and information systems.
- k) Review and pre-approve any non-audit services to be provided by the external auditors’ firm and consider the impact on the independence of the auditors; between scheduled meetings, the Chair is authorized to approve all audit related services and non-audit services provided by the external auditors for individual engagements with estimated fees of \$25,000 and under; and shall report all such approvals to the Committee at its next scheduled meeting.
- l) Review and approve all related-party transactions of the Company.
- m) Review, at least annually, and more frequently if necessary, the Company’s policies for risk assessment and risk management (the identification, monitoring, and mitigation of risks).
- n) Inquire of management and the independent auditor about significant business, political, financial and control risks or exposure to such risk.
- o) Request the external auditor’s opinion of management’s assessment of significant risks facing the Company and how effectively they are being managed or controlled.

- p) Assess the effectiveness of the over-all process for identifying principal business risks and report thereon to the Board.
- q) Perform such other functions as assigned by law, the Company's bylaws or as the Board deems necessary and appropriate.

**6. Committee Meetings and Board Reporting**

Meetings will be held as required, but not less than quarterly. Minutes will be recorded and reports of committee meetings will be presented at the next regularly scheduled Board meeting.

**7. Committee Charter Review and Approval**

This Audit Committee Charter shall be reviewed, reassessed, and approved by the Board annually.

**8. Whistleblower Policy**

The Committee shall establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by the Company's employees of concerns regarding questionable accounting or auditing matters, or other matters of concern, related to the policies of the Company as set out in the attached Schedule A.

***Exhibit "A"***  
***To the Audit Committee Charter***

***Procedures for the Submission of Complaints or Concerns Regarding  
Accounting, Internal Accounting Controls, Auditing Matters***

The Audit Committee of the board of directors of **ALPHA COGNITION INC.** (the "Company") has established procedures for: (a) the receipt, retention, and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters; and (b) the submission by employees of the Company and others, on a confidential and anonymous basis, of concerns regarding questionable accounting or auditing matters.

In accordance with National Instrument 52-110, the Audit Committee has adopted the following procedures:

1. The Company shall promptly forward to the Audit Committee any complaints that it has received regarding financial statement disclosures, accounting, internal accounting controls or auditing matters.
2. Any employee of the Company may submit, on a confidential, anonymous basis if the employee so desires, any concerns (the "concern") regarding financial statement disclosures, accounting, internal accounting controls or auditing matters, or other matters of concern, related to the policies of the Company. All such concerns shall be set forth in writing and forwarded in a sealed envelope to the Chairman of the Audit Committee, in care of the Company's Chairman at:

ALPHA COGNITION INC.  
#301 – 1228 Hamilton Street  
Vancouver, BC V6B 6L2  
Attention: Chairman of the Audit Committee  
Email: info@alphacognition.com

If an employee would like to discuss the concern with a member of the Audit Committee, the employee should indicate this in the submission and include a telephone number at which he or she might be contacted if the Audit Committee deems it appropriate.

3. Following the receipt of any concern submitted hereunder (the "submission"), the Audit Committee will investigate each matter so reported and take such steps, actions or institute such procedures as the Audit Committee deems appropriate.
4. The Audit Committee may enlist employees of the Company and/or outside legal, accounting, or other advisors, as appropriate, to conduct any investigation of the submission and such other outside advisors shall use reasonable efforts to protect the confidentiality and anonymity of the complainant.
5. The board of directors stands behind this policy and guarantees that no retaliation of any kind will be taken or permitted to be taken against employees with respect to any submission made in good faith.
6. The Audit Committee shall retain the submission and the documentation related thereto as part of the records of the Audit Committee.

**AUDIT COMMITTEE**  
**ALPHA COGNITION INC.**



## **Schedule “B”**

### **RISK FACTORS**

Investing in our Common Shares involves a high degree of risk. Prospective investors should carefully consider the risks described below, together with all of the other information included or referred to in this AIF, before purchasing Common Shares. The risks set out below are not the only risks we face. Additional risks and uncertainties not presently known to us or not presently deemed material by us might also impair our operations and performance. If any of these risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our Common Shares could decline and investors in our Common Shares could lose all or part of their investment.

#### **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 June 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 acquiring 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.

#### **Risks Related to Our Financial Condition**

***We are a clinical-stage biopharmaceutical company in the early stages of development with no products approved for commercial sale and have incurred significant losses since our inception. We expect to incur significant losses over for the foreseeable future and our costs may increase substantially in the foreseeable future.***

Since our inception, we have incurred significant net losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were \$12.1 million and \$19.6 million for the years ended December 31, 2022 and 2021, respectively. As of March 31, 2023 the most recently filed quarterly reporting, we had an accumulated deficit of \$51.7 million. Our clinical trials and operations have been funded which has been primarily financed by equity. We have no products approved for commercialization and have never generated any revenue from product sales.

We have devoted substantially all our financial resources and efforts to the development of our product candidates, including conducting preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses until we have achieved sufficient sales from a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. Factors that may significantly increase our foreseeable expenses include:

- our ongoing and planned clinical trials of ALPHA-1062, as well as our plans to initiate and complete additional clinical trials;
- advancing regulatory approval of ALPHA-1062 for the treatment of mild-to-moderate Alzheimer's Disease;
- continuing clinical validation of ALPHA-1062 for moderate-to-severe Alzheimer's Disease and exploring the potential related to cognitive impairment with TBI; and
- establishing a commercialization infrastructure and scaling up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including ALPHA-1062.

***Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the development and commercialization of our product candidates, if approved.***

To generate revenue and become and remain profitable, we must succeed in developing and eventually commercializing product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities, other than our planned NDA submission of ALPHA-1062 in Alzheimer's Disease. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations.

***We have not yet completed an Alzheimer's Disease patient tolerability study for ALPHA-1062, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.***

We commenced operations in 2014, and to date, we have not yet demonstrated our ability to successfully complete an Alzheimer's Disease patient tolerability study for ALPHA-1062, obtain regulatory approvals, manufacture a product on a commercial scale or arrange for a third party to do so on our behalf. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

***We will need substantial capital to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.***

Our operations have required substantial amounts of capital since inception, and we expect our expenses to increase significantly in the foreseeable future. Identifying 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 complete our ongoing clinical trials of our product candidates, initiate future clinical trials of our product candidates, seek marketing approval for ALPHA-1062 for mild-to-moderate Alzheimer's Disease, prepare for commercialization activities 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 June 26, 2023, we had \$1.4 million in cash and cash equivalents 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.

## **Risks Related to Our Business Development**

***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 advancement 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.

***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 the TBI Company. The establishment and funding of the TBI Company as described in this AIF are at the proposal stage only. There is no guarantee that the Company will be successful at launching the TBI Company as a separately funded entity as described in this AIF or at all. If successfully launched, there is no guarantee that the TBI Company will be successful in advancing the ALPHA-1062 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 the TBI Company. 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 the TBI Company. Even if the Company is able to out-license its technology or intellectual property to the TBI Company, 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 the TBI Company could have a material adverse effect on the Company's financial condition, results of operations, and prospects.

***We have initially concentrated our research and development efforts on the treatment of Alzheimer's Disease, a disease that has seen limited success in drug development.***

Efforts by biopharmaceutical and pharmaceutical companies in treating Alzheimer's Disease have seen limited success in drug development. Only one disease-modifying therapeutic option has been approved by the FDA. Biogen's Aduhelm®, a monoclonal antibody administered via infusion, received accelerated approval from the FDA on June 7, 2021. Adlarity®, transdermal formulation of donepezil from the makers of Corium, was the most recently FDA approved symptomatic treatment in 8 years, in March 2022. We cannot be certain that our oral, small-molecule approach will lead to the development of approvable or marketable products. Since 2003, over 500 clinical studies have been completed and only Aduhelm® and Adlarity® have been approved by the FDA, compared to a success rate of 50% to 80% for all other drug candidates. The FDA could conduct a longer than expected regulatory review process, increased expected development costs or the delay or prevention of commercialization of ALPHA-1062 for the treatment of mild-to-moderate Alzheimer's Disease.

***We may encounter substantial delays in our preclinical studies and clinical trials or may not be able to conduct or complete our preclinical studies or clinical trials on the timelines we expect, if at all.***

Clinical trials are expensive and can take many years to complete, and the outcome is inherently uncertain. The historical failure rate for product candidates in our industry is high. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage and our future clinical trials may not be successful. Clinical trials can be delayed or terminated for a variety of reasons.

***The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.***

Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. For instance, we do not know whether ALPHA-1062 will perform in current or future clinical trials as ALPHA-1062 has performed in preclinical studies or earlier clinical trials. Product candidates in clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidates due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing other therapies and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

***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 revenue 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.

***We rely on third parties in the conduct of all of our clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.***

We currently do not have the ability to independently conduct clinical trials that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements or GCP requirements. The FDA and regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical trials play a significant role in the conduct of these studies and the subsequent collection and analysis of data. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLPs or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our business, financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

***Use of our therapeutic candidates could be associated with side effects, adverse events or other properties or safety risks, which could result in significant negative consequences that could severely harm our business, prospects, operating results and financial condition***

Adverse events or other undesirable side effects caused by our product candidates or related to procedures conducted as part of the clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If unacceptable side effects arise in the development of our product candidates, we, the FDA, the Institutional Review Boards at the institutions in which our studies are conducted or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. In addition, our patient tolerability study and other clinical trials may only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, our product candidates may cause unforeseen safety events when evaluated in larger patient populations. Further, clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our business, financial condition, results of operations and prospects.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranty. Claims could also be asserted under local consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources.

If we are unable to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims, the commercialization of our current or any future product candidates we develop could be inhibited or prevented. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

***Significant disruptions of our information technology systems, breaches of data security and other incidents could materially adversely affect our business, results of operations and financial condition.***

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The costs to us to investigate, mitigate and remediate security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and these risks could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs.

***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.***

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any of our product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that are currently in market or pursuing the development of product candidates for the treatment of the diseases and disorders for which we have research programs, including Alzheimer's Disease, cognitive impairment with TBI, and Amyotrophic Lateral Sclerosis. Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

#### **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.***

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 market opportunities for ALPHA-1062, if approved, may be smaller than we anticipate.***

We expect to initially seek approval for ALPHA-1062 for mild-to-moderate Alzheimer's Disease. Our estimates of market potential have been derived from a variety of sources, including scientific literature, patient foundations and market research and may prove to be incorrect. Even if we obtain significant market share for ALPHA-1062 after FDA approval, the potential target populations may be too small to consistently generate revenue, and we may never achieve profitability without obtaining marketing approval for additional indications.

***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 the inspection of 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.



***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.***

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our third-party manufacturers will be successful in establishing a larger-scale commercial manufacturing process for our product candidates which achieves our objectives for manufacturing capacity and cost of goods. In addition, there is no assurance that our third-party manufacturers will be able to manufacture our product candidates to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of such products or to meet potential future demand. Our failure to properly or adequately scale scaling up manufacturing for commercial scale would adversely affect our business, results of operations and financial condition.

***The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production, due to supply chain disruptions, compliance and regulatory matters, Good Manufacturing Practices (GMP), Quality Control (QC), and environmental risks. If any of our third-party manufacturers encounter such difficulties, our ability to provide 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, 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.

Any problems with the manufacturing process, such as deviations from standard operating procedures or difficulties in scaling up production, can impact the quality, safety, and efficacy of pharmaceutical products, leading to product recalls or delays in commercialization.

Manufacturing difficulties can include:

- Supply chain disruptions: Disruptions in the supply chain, such as shortages of raw materials, transportation issues, or delays in regulatory approvals, can negatively impact the production and distribution of pharmaceutical products, leading to revenue loss and reputational damage.
- Compliance and regulatory risks: The pharmaceutical industry is highly regulated, and any failure to comply with regulations can result in legal and financial penalties, as well as damage to the Company's reputation.
- CMC-related regulations include Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP).
- Quality control and product safety risks: Any issues related to the quality, purity, or stability of pharmaceutical products can impact their safety and efficacy, leading to adverse events or product recalls. It is critical for pharmaceutical companies to maintain robust quality control systems to ensure the safety and efficacy of their products.

- Environmental risks: Pharmaceutical manufacturing can have environmental impacts, including the generation of hazardous waste and the release of pollutants into the air and water. Failure to manage these risks adequately can result in legal and financial liabilities, as well as reputational damage.

***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.***

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Even if we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our investment in the development of product candidates.

BioPharma companies may face risks related to healthcare laws, Medicare, and other government programs, which can have significant implications for their business operations, financial performance, and reputation. Some potential risk factors related to healthcare laws and government programs:

- Changes in healthcare laws and regulations: Healthcare laws and regulations are subject to change, which can impact the pharmaceutical industry. Any new laws or regulations related to drug pricing, access to healthcare, or insurance coverage can impact the demand for pharmaceutical products, leading to revenue loss and reputational damage.
- Compliance risks related to government programs: Biopharma companies that during commercialization participate in government programs, such as Medicare and Medicaid, are subject to numerous regulations and compliance requirements. Any failure to comply with these requirements can result in legal and financial penalties, as well as damage to the Company's reputation.
- Reimbursement risks: The reimbursement of pharmaceutical products by government programs, such as Medicare and Medicaid, can impact the demand for pharmaceutical products. Any changes in reimbursement rates or policies can impact the Company's revenue and profitability.
- Pricing risks: The pricing of pharmaceutical products is subject to scrutiny by government agencies, healthcare providers, and consumers. Any allegations of price gouging or other pricing improprieties can lead to negative publicity, regulatory investigations, and legal liabilities.

***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.***

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.

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

***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.

***If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.***

Our commercial success will largely depend on our ability to obtain market exclusivity in the United States and other countries with respect to our drug candidates and their target indications. Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, certain of our product candidates may be eligible for marketing exclusivity. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity, or NCE. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products and launch their product earlier than might otherwise be the case.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might harm our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products, and may subject us to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims, which could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

### **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.***

Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Obtaining approval by the FDA and other comparable foreign regulatory authorities is costly, unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

***The FDA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.***

Our ongoing clinical trials are being undertaken in the United States. We may choose to conduct additional clinical trials internationally. The acceptance of study data by the FDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

***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.***

The commercial potential for our approved products, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and biologics. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in

the United States or abroad. If we or any related third parties are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or any related third parties are not able to maintain regulatory compliance, ALPHA-1062 or any future product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would materially affect our business, financial condition and results of operations.

### **Risks Related to Employee Matters and Growth Management**

*We will need to increase the size of our organization, and we may experience difficulties in managing growth.*

As of June 26, 2023, we had a collective total of 5 full-time, part-time employees/contractors. We also use third party consultants and contractors to support our operations. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize ALPHA-1062, our lead product candidate, or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize ALPHA-1062, if approved, and our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

*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, Michal McFadden, 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.

### **Risks Related to Our Common Shares and Warrants**

*Our stock price may be volatile and you may not be able to resell Common Shares at or above the price you paid.*

The trading price of our Common Shares could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In particular, the trading prices for biopharmaceutical companies have been highly volatile as a result of Canada, the United States economies and world events. In addition, the stock markets in general, and the markets for biopharmaceutical stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our Common Shares.

***An active, liquid and orderly market for our Common Shares is currently limited and may not develop further, and you may not be able to resell your Common Shares at or above the public offering price.***

Prior to this AIF, there has been limited trading of our Common Shares on the TSX-V, CSE and OTCQB exchanges. In addition, an active trading market may not further develop or may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other product candidates, businesses or technologies using our shares as consideration.

***We believe that we may be a “passive foreign investment company” for the current taxable year which may result in materially adverse United States federal income tax consequences for United States investors.***

We generally will be designated as a “passive foreign investment company” under the meaning of Section 1297 of the United States Internal Revenue Code of 1986, as amended (a “PFIC”) if, for a tax year, (a) 75% or more of our gross income for such year is “passive income” (generally, dividends, interest, rents, royalties, and gains from the disposition of assets producing passive income) or (b) if at least 50% or more of the value of our assets produce, or are held for the production of, passive income, based on the quarterly average of the fair market value of such assets. United States shareholders should be aware that we believe we were classified as a PFIC during our tax year ended December 31, 2021, and based on current business plans and financial expectations, believe that we may be a PFIC for the current and future taxable years. If we are a PFIC for any year during a U.S. shareholder’s holding period, then such U.S. shareholder generally will be required to treat any gain realized upon a disposition of Common Shares, or any “excess distribution” received on its Common Shares, as ordinary income, and to pay an interest charge on a portion of such gain or distribution, unless the shareholder makes a timely and effective “qualified electing fund” election (“QEF Election”) or a “mark-to-market” election with respect to the Common Shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of our net capital gain and ordinary earnings for any year in which we are a PFIC, whether or not we distribute any amount to our shareholders. A U.S. shareholder who makes a mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the Common Shares over the taxpayer’s basis therein. U.S. Holders should be aware that there can be no assurance that the Company will satisfy record keeping requirements that apply to a QEF, or that the Company will supply U.S. Holders with information that such U.S. Holders require to report under the QEF rules, in the event the Company is a PFIC and a U.S. Holder wishes to make a QEF Election. Accordingly, U.S. Holders may not be able to make a QEF Election with respect to their Common Shares. This paragraph is qualified in its entirety by the discussion below under the heading “Certain United States Federal Income Tax Considerations.” Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership, and disposition of Common Shares.

***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 operating and capital expenditures beyond the date that is months after the date of this AIF, 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.

***Concentration of ownership of our Common Shares among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions.***

Our executive officers, directors and current beneficial owners of 5% or more of our Common Shares and their respective affiliates beneficially own approximately 33.4% of our outstanding Common Shares and Restricted Shares as of the date of this AIF. As a result, these persons, acting together, would be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these shareholders purchased their shares at prices substantially below the current market price of our Common Shares and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders.

***Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.***

At December 31, 2022, the Company had, for Canadian tax purposes, non-capital losses aggregating approximately \$32.3 million. These losses are available to reduce taxable income earned by the Alpha Canada in future years and expire between 2035 and 2042.

In general, under Section 382 of the U.S. Tax Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards (“NOLs”) to offset future taxable income. Similarly, where control of a corporation has been acquired by a person or group of persons, subsection 111(5) of the Canadian Income Tax Act and equivalent provincial income tax legislation restrict the corporation’s ability to carry forward non-capital losses from preceding taxation years. Our existing NOLs may be subject to limitations arising from previous ownership changes. Future changes in our share ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the U.S. Tax Code or an acquisition of control for the purposes of subsection 111(5) of the Canadian Income Tax Act, and adversely affect our ability to utilize our NOLs in the future. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

***We do not currently intend to pay dividends on our Common Shares, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our Common Shares.***

We do not currently intend to pay any cash dividends on our Common Shares for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your Common Shares for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our Common Shares. There is no guarantee that our Common Shares will appreciate or even maintain the price at which our holders have purchased it.

***The Company has outstanding warrants denominated in both Canadian and U.S. Dollars. The foreign exchange risk associated with the variable of the Canadian Dollar denominated warrant and the Company's resulting U.S. Dollar denominated functional currency could result in a significant risk of loss at the date of valuing the risk and cause the Company to incur a significant non-cash derivative liability depending on the exchange rate and share price volatility, share price, risk-free interest rate, and remaining life of the Canadian Dollar denominated warrants.***

As at the date of this filing, the Company has outstanding warrants denominated in both Canadian and U.S. Dollars. Based on the plans of the Company to raise future capital through the U.S. capital markets, it is reasonable to assume the Company's functional currency will change from the Canadian Dollar to the U.S. Dollar. If this occurs, Canadian Dollar denominated warrants will cause the Company to assess the foreign exchange risk associated with the variable of the Canadian Dollar denominated warrant and the Company's resulting U.S. Dollar denominated functional currency. This could result in a significant risk of loss at the date of valuing the risk and cause the Company to incur a significant non-cash derivative liability depending on the exchange rate and share price volatility, share price, risk-free interest rate, and remaining life of the Canadian Dollar denominated warrants.