ALPHA COGNITION INC.

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Annual Information Form

For the year ended December 31, 2023

Dated as of April 30, 2024

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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, 2023.

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, 2023 and 2022, 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, 2023 (the "**Annual MD&A**").

Copies of documents incorporated by reference are available under the Company's profile on the SEDAR+ website at www.sedarplus.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contained in a document incorporated or deemed to be incorporated by reference herein will be deemed to be modified or superseded for the purposes of this AIF to the extent that a statement contained in this AIF or in any subsequently filed document that also is or is deemed to be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 Any statement so modified or superseded will not constitute a part of this AIF, except as so modified or superseded. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes.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of such a modifying or superseding statement will not be deemed an admission for any purpose that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be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.

All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed in, or implied by these, forward-looking statements and therefore, you should not unduly rely on such statements, including, but not limited to:

- risks related to early stage of development and significant history of losses;
- risks related to our ability to generate revenue and achieve profitability;
- risks related to our lack of history in commercializing products;
- risks related to our need for substantial additional capital;
- risks related to fluctuations in currency exchange rates;
- risks related to our reliance on the successful development, regulatory approval and commercialization of ALPHA-1062;
- risks related to our ability to successfully expand our pipeline of product candidates;
- risks related to our focus on treatments for Alzheimer's Disease;
- risks related to substantial delays in our preclinical and clinical trials;
- risks related to the outcome of preclinical testing and early clinical trials not being predictive of later clinical trials;

- risks related to our reliance on third-parties to conduct our clinical trials;
- risks related to use of our therapeutic candidates being associated with side effects, adverse events or other properties or safety risks;
- risks related to preliminary data from studies or trials we announce changing as more data becomes available and are subject to audit and verification processes;
- risks related to foreign jurisdictions not accepting the data from our trials in the United States;
- risks related to product liability;
- risks related to our information systems;
- risks related to research and development of pharmaceuticals being lengthy and inherently risky;
- risks related to disruptions at the FDA;
- risks related to our failure to comply with health and data protection laws;
- risks related to approval in foreign jurisdictions;
- risks related to competition in our industry;
- risks related to commercialization and manufacturing;
- risks related to our market opportunity being smaller than we anticipate;
- risks related to our reliance on third-party suppliers;
- risks related to supply chain risks;
- risks related to our products never having been manufactured on a commercial scale;
- risks related to the complexity of manufacturing drugs;
- risks related to the successful commercialization of our product being dependent on governmental authorities and health insurers establishing adequate coverage, reimbursement levels and pricing policies;
- risks related to our lack of a sales organization;
- risks related to our ability to obtain and maintain patent protection for our technology and product candidates;
- risks related to protecting our intellectual property rights throughout the world;
- risks related to obtaining protection under Hatch-Waxman Amendments;
- risks related to the validity, scope and enforcement of any patents listed in the Orange Book;
- risks related to maintaining our patent protections;
- risks related to our need to license intellectual property from third parties;
- risks related to third party claims of infringement;
- risks related to our ability to identify third-party patents to avoid infringement;
- risks related to lawsuits to protect and enforce our patents;
- risks related to unfavorable publicity;
- risks related to intellectual property litigation using substantial resources and distracting personnel;
- risks related to changes in U.S. patent law;
- risks related to sharing our trade secrets;
- risks related to claims that our employees, consultants or independent contractors have wrongfully used confidential information of former employers;
- risks related to claims we wrongfully hired employees;
- risks related to claims challenging inventorship;
- risks related to trademarks;
- risks related to trade secrets;
- risks related to regulatory approval processes being lengthy, time consuming and unpredictable;
- risks related to our products remaining subject to regulatory scrutiny;
- risks related to obtaining and maintaining regulatory approval in multiple jurisdictions;
- risks related to using accelerated pathways to FDA approval;
- risks related to healthcare legislation including unfavorable pricing;
- risks related to our business exposing us to regulatory penalties;

- risks related to insufficient funds at the FDA or SEC;
- risks related to our ability to comply with environmental, health and safety laws and regulations;
- risks related to U.S. foreign export and import laws;
- risks related to our need to increase the size of our organization;
- risks related to our need to attract and retain management and key scientific personnel;
- risks related to our employees or contractors violating the law or engaging in misconduct;
- risks related to establishing sales and marketing personnel;
- risks related to exploring strategic collaborations; and
- risks related to acquisitions and related integrations.

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 United States 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, 2023;

"**Alpha**" or the "**Company**" means Alpha Cognition 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.;

"**Alpha Seven**" means Alpha Seven Therapeutics 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;

"**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;

"**COO**" means the Chief Operating 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;

"**Escrow Agreement**" means the escrow agreement dated March 18, 2021, between the Company, Computershare and certain escrow shareholders;

"**Exchange Act**" means the United States *Securities Exchange Act of 1934*;

"**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 nominating committee of the Board;

"**Hatch-Waxman Amendments**" means the Drug Price Competition and Patent Term Restoration Act of 1984;

"**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 were 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;

"**Orange Book**" means the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations;

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

"**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 Plus;

"**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; and

"**USPTO**" means the United States Patent and Trademark Office.

CORPORATE STRUCTURE

Name, Address and Incorporation

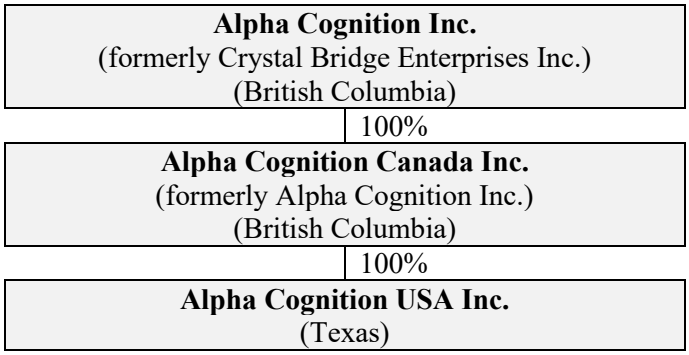
The Company was incorporated on November 15, 2017, under the *Business Corporations Act* (British Columbia) ("**BCBCA**") under the name "Crystal Bridge Enterprises Inc.". The Company is a reporting issuer in all of the provinces and territories of Canada, and its Common Shares are listed for trading 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. ("**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 c/o 1200 – 750 West Pender Street, Vancouver, BC, V6C 2T8. 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. 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:

2021 Financial Year

March 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.

April 2021 - the Company appointed Mr. Michael McFadden as Chief Executive Officer and Mr. Len Mertz as Chairman.

May 2021 - the Company appointed Ms. Lauren D'Angelo as Chief Commercial Officer, as part of the Company's plan to further develop the operational and commercialization team. Ms. D'Angelo was promoted to COO in October 2023.

August 2021 - the Company's Common Shares were approved for quotation on the OTCQB Venture Market under the symbol "ACOGF".

September 2021 - the FDA accepted the Company's IND 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 allowed the Company to submit an NDA 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.

October 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 consisted of one Common Share of the Company and one Common Share purchase warrant. Each warrant entitled 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**"). The Listed Warrants expired on October 1, 2023.

October 2021 - the Company formed a Scientific Advisory Board, engaged Bello Capital Partners to provide strategic digital media services and Wealth Securities Limited as a market-maker.

December 2021 - the Company appointed 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.

December 2021 - the Company received 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.

December 2021 - Dr. Fred Sancilio resigned from his role as a director and as President of the Company.

2022 Financial year

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

April 2022 - the Company appointed Don Kalkofen as Chief Financial Officer of the Company and Michael McFadden, the Company's Chief Executive Officer, to the Board.

During April 2022 - the Company made the following program developments:

- ALPHA-1062 for mild to moderate dementia of the Alzheimer's type
  - The Company 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.

- ALPHA-0602 for ALS
  - 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 released 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 released 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.

May 2022 - 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.

May 2022 - the Company granted 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 C$0.64 per share and expire ten years from the date of grant, subject to certain vesting provisions.

June 2022 - the Company received 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.

August 2022 - the Company received 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.

- 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 extended release 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, Cmax 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.

November 2022 - the Company provided the following corporate updates:

- 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 ALPHA1062 in mild-to-moderate Alzheimer's Disease.
- 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.

2023 Financial Year

January 2023 - the Company cancelled 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.

February 2023 - the Company 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.

March 2023 - the Company 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 was comprised of 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$6,100,000 (US$4,500,000) through the sale of an aggregate 23,747,648 units. 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.

March 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.

April 2023 - the Company received final approval from the CSE to list its Common Shares and its 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" on the CSE and the Listed Warrants were trading under the symbol "ACOG.WT" on the CSE until they expired on October 1, 2023.

May 2023 - the Company commenced a best efforts private placement offering of up to US$6,500,000 of units. 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 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 was 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 Company agreed to 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 was also entitled to earn and receive additional Common Shares of the Company.

June 2023 - the Company was awarded a US$750,000 grant from the Army Medical Research and Material 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.

June 2023 - the Company granted 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.

August 2023 - the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance to the Company for patent application No. 17/575,025, titled "Solid Forms of ALPHA-1062 Gluconate" which includes claims covering protection for crystalline solid forms of ALPHA-1062 and bolsters existing patents that the Company holds.

August 2023 - the Company engaged Frontier Flex Marketing to provide market making services.

September 2023 - the Company completed the NDA submission to the FDA for ALPHA-1062. The NDA submission is based on results from the previous four studies the Company conducted demonstrating bioequivalence for ALPHA-1062 to galantamine and galantamine extended release. Adverse events documented across all studies for ALPHA-1062 were less than 2% and no insomnia was observed.

December 2023 - the FDA accepted the Company's NDA for ALPHA-1062. The NDA has been granted a Prescription Drug User Fee Act (PDUFA) goal date of July 27, 2024. This date refers to the deadline set by the FDA for reviewing the NDA and making a final decision on marketing approval.

December 2023 - the Company entered into an agreement with Planet Ventures Inc. for the provision of investor relations and communication services. The agreement is for a term commencing on December 20, 2023 and expiring on December 30, 2024, and the Company paid Planet Ventures Inc. a one-time cash fee of C$160,000.

During the second half of 2023, and during January 2024 as described below under the heading "2024 Current Financial Year", the Company raised an aggregate of US$8,450,000 (including the 30% over-allotment option granted to Spartan) through the issuance of 38,409,087 units at a price of US$0.22 per unit, as follows:

- August 31, 2023 - the Company closed the first tranche of its private placement for gross proceeds of US$1,345,093.04 through the issuance of 6,114,058 units. Each unit consists of a Common Share and a half warrant, with each whole warrant entitling the holder to purchase an additional Common Share at a price of US$0.31 for a period of three years. Spartan received cash compensation of US$180,051 and 272,803 compensation warrants of the Company, exercisable on the same terms as the private placement warrants.
- October 2023 - the Company closed the second tranche of its private placement for gross proceeds of US$351,303 through the issuance of 1,596,830 units. Each unit consists of a Common Share and a half warrant, with each whole warrant entitling the holder to purchase an additional Common Share at a price of US$0.31 for a period of three years. Spartan received cash compensation of US$51,600 and 78,181 compensation warrants of the Company, exercisable on the same terms as the private placement warrants.
- November 2023 - the Company closed the third tranche of its private placement for gross proceeds of US$1,009,999 through the issuance of 4,590,903 units. Each unit consists of a Common Share and a half warrant, with each whole warrant entitling the holder to purchase an additional Common Share at a price of US$0.31 for a period of three years. Spartan received cash compensation of US$151,500 and 229,544 compensation warrants of the Company, exercisable on the same terms as the private placement warrants. The Company also paid a consulting fee of US$160,000 pursuant to the Consulting Agreement.

- December 2023 - the Company closed the fourth tranche of its private placement for gross proceeds of US$2,011,138 through the issuance of 9,141,534 units. Each unit consists of a Common Share and a warrant, with each warrant entitling the holder to purchase an additional Common Share at a price of US$0.31 for a period of three years. Spartan received cash compensation of US$238,515 and 722,771 compensation warrants of the Company, exercisable on the same terms as the private placement warrants.

2024 Current Financial Year

January 2024 - the Company closed the final tranche of its private placement for gross proceeds of US$3,732,467 through the issuance of 16,965,762 units. Each unit consists of a Common Share and a warrant, with each warrant entitling the holder to purchase an additional Common Share at a price of US$0.31 for a period of three years. Spartan received cash compensation of US$342,320 and 1,037,330 compensation warrants of the Company, exercisable on the same terms as the private placement warrants. The Company also paid a consulting fee of US$320,000 and issued 14,558,285 Common Shares to Spartan pursuant to the Consulting Agreement. The Company paid to certain other finders aggregate cash commission of US$48,858, being 6% of the gross proceeds raised under the offering from investors introduced to the Company by such finders.

February 2024 - the Company filed a new composition-of-matter patent to secure broad protection for ALPHA-1062, which is currently under review by the FDA for mild-to-moderate Alzheimer's Disease. The composition-of-matter patent application is filed for approval with the United States Patent and Trademark Office (USPTO) and may be extended internationally and, if approved, will secure composition-of-matter protection for the oral formulation of ALPHA-1062 until 2044.

DESCRIPTION OF THE BUSINESS

General

The Company is a pre-commercial, biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's Disease, for which there are limited or no treatment options. The Company is focused on the development of ALPHA-1062 for the treatment of mild-to-moderate Alzheimer's Disease following the recent New Drug Application ("**NDA**") submission and acceptance by FDA. The Company is now focused on FDA review of the NDA, approval, and subsequent commercial sales of ALPHA-1062 oral tablet formulation. The Company's ALPHA-1062 development program is primarily focused on clinical and regulatory development, Chemistry, Manufacturing and Control (CMC) development, and commercial readiness. The Company has three additional development programs: ALPHA-1062 in combination with memantine for the treatment of moderate-to-severe Alzheimer's Disease, ALPHA-1062 sublingual formulation, ALPHA-1062 intranasal ("**ALPHA-1062IN**") formulation for the treatment of cognitive impairment with mild traumatic brain injury (mTBI; otherwise known as concussion) and ALPHA-0602, ALPHA-0702 and ALPHA-0802, also referred to as 'Progranulin' and 'Progranulin GEM's', for the treatment of neurodegenerative diseases including amyotrophic lateral sclerosis, otherwise known as ALS or Lou Gehrig's disease and spinal muscular atrophy (SMA).

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

Preclinical stage assets include ALPHA-0602, ALPHA-0702 and ALPHA-0802 (Progranulin and Progranulin GEM's), which are expressed in several cell types in the central nervous system and in peripheral tissues, promotes cell survival, regulates certain inflammatory processes, and play a significant role in regulating lysosomal function and microglial responses to disease. Its intended use for the treatment of neurodegenerative diseases has been patented by the Company and ALPHA-0602 has been granted an Orphan Drug Designation for the treatment of ALS by the FDA. ALPHA-0702 and ALPHA-0802 are Granulin Epithelin Motifs, ("**GEMs**"), derived from full length progranulin which have therapeutic potential across multiple neurodegenerative diseases. GEMs have been shown to be important in regulating cell growth, survival, repair, and inflammation. ALPHA-0702 and ALPHA-0802 are designed to deliver this with potentially lower toxicity, and greater therapeutic effect. As the assets are pre-clinical assets and do not add material value to the Company, the Company will not develop these assets further and instead will seek to out-license the assets to interested third parties. Given the early stage of discussion with third parties, the Company cannot assess value to a license agreement.

TBI Out-License

The Company obtained shareholder approval to out-license ALPHA-1062IN for applications in treating mild traumatic brain injury ("**mTBI**") and TBI to Alpha Seven Therapeutics Inc. ("**Alpha Seven**") a newly incorporated entity. Alpha Seven will focus its business on the advancement of the use of ALPHA-1062IN for the treatment of TBI and mTBI with a focus on using intra-nasal delivery, including development and manufacturing work, completing a pre-clinical toxicity study, and advancing to clinical trials and potential FDA approval. The establishment of Alpha Seven provides for the separate funding and advancement of the TBI and mTBI 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. Alpha Seven Therapeutics was incorporated in Delaware in July 2023. The out-license of ALPHA-1062IN technology has not yet occurred.

The Company met with the U.S. Food and Drug Administration ("**FDA**") in a pre-investigational new drugs ("**IND**") meeting in the second quarter of 2023. The meeting was scheduled to align with FDA on pre-clinical, clinical, and manufacturing items necessary to file an IND and initiate a Phase 2 trial for ALPHA-1062IN. As a result of FDA feedback, Alpha Seven intends to complete additional manufacturing and toxicity work which the Company believes will allow Alpha Seven to advance the program to file an IND with the FDA. Additional capital will be needed to advance the manufacturing, toxicity work, and future clinical trials.

Our Markets and Opportunities

The Company is dedicated to developing treatments for under-served neurodegenerative diseases, specifically Alzheimer's Disease, mTBI and TBI through our out licensing agreement with Alpha Seven.

Alzheimer's Disease Mild-to-Moderate Stage & Moderate-to-Severe Market

An estimated 6.7 million Americans age 65 and older are living with Alzheimer's Disease in 2023, and often causes burdensome effects on their families and caregivers. It is by far the most common form of dementia, estimated to be 60% to 80% of all diagnosed cases. Treatment options for Alzheimer's Disease are limited, and health care professionals along with patients/caregivers are generally dissatisfied with the currently available treatments due to limited efficacy and unmanageable tolerability from adverse events.

Of the patients with Alzheimer's Disease, the vast majority, approximately 2.5 million, have been diagnosed with mild Alzheimer's Disease. Mild Alzheimer's Disease is expected to grow over the next decade, signaling a continued need for symptomatic drugs with greater efficacy and fewer side effects.

Current acetylcholinesterase inhibitor medications are absorbed in the gastrointestinal system and bind to locally present acetylcholinesterase, the enzyme responsible for breaking down the neurotransmitter, acetylcholine. The local acetylcholine levels are then increased, and the neurons associated with the gastrointestinal system become overstimulated. The result is an increase of gastrointestinal side effects (nausea, vomiting, diarrhea).

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 more 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.

Alzheimer's Disease Moderate-to-Severe Stage Market

Of the approximately 3.9 million people that have been diagnosed with Alzheimer's Disease, the moderate-to-severe market size is approximately 1.4 million people in the U.S. (moderate Alzheimer's Disease accounts for approximately 899 thousand patients and severe Alzheimer's Disease affects approximately 508 thousand patients). In the moderate stage of Alzheimer's Disease symptoms becomes more intense, significantly affecting their everyday life. They have difficulties with communication and personality and behavioral changes present. It's estimated that 61% of Alzheimer's Disease patients living in a nursing home are in the moderate to severe stages of the disease. On average, 40% of the final years of an Alzheimer's Disease patient's life will be spent in the severe stage of the disease and majority will have to be place in a long-term care home due to the immense burden this stage places on family members and caregivers. According to third-party market research conducted by Infinity Group in July 2021, many providers and caregivers believe the approved generic medications provide limited efficacy and adverse effects.

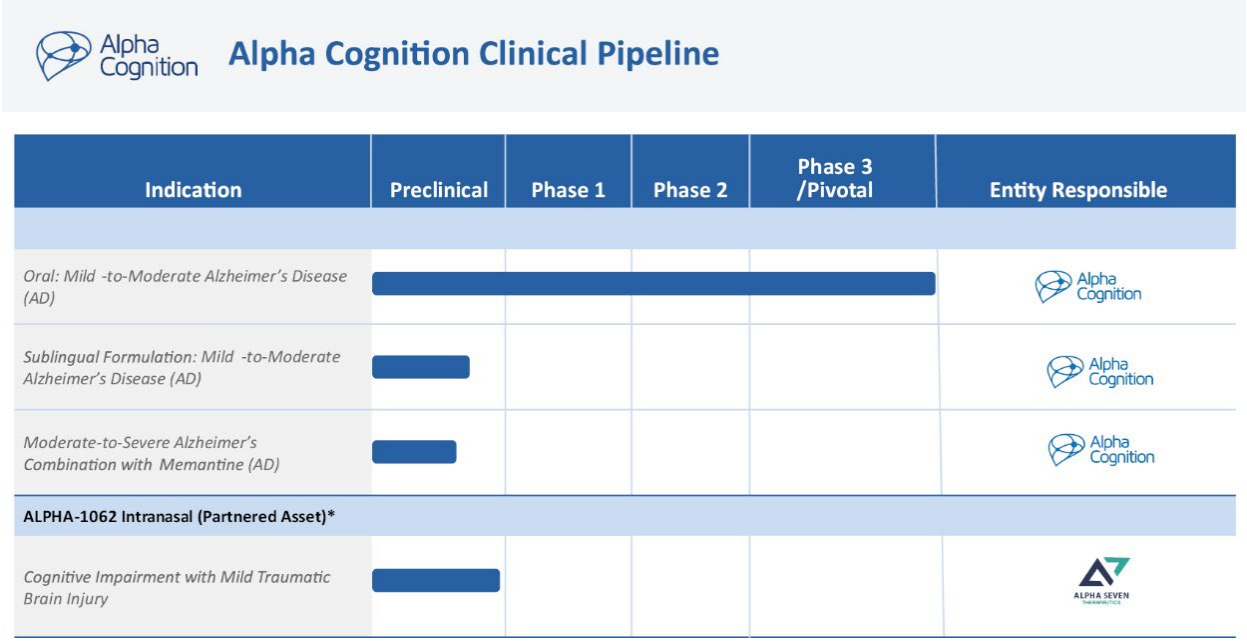
Traumatic Brain Injury (TBI) Market

According to a secondary market research report by Decision Resources Group/Clarivate paid for by the Company, Traumatic Brain Injury (TBI) is a highly prevalent, and increasingly common condition, with nearly 3 million diagnosed events occurring in the United States alone in 2019, and 91% of events are mild TBI. Based on hospitalizations and emergency room visits data reported by the Brain Injury

Association of America, we estimate that 79% of these diagnosed annual events are adults. Residual Traumatic Brain Injury symptoms may impact patient Quality of Life, social relationships, and ability to work. Approximately 50% of mTBI patients have persistent cognitive dysfunction (McInnes K, Friesen CL, MacKenzie DE, Westwood DA, Boe SG. Mild Traumatic Brain Injury (mTBI) and chronic cognitive impairment: A scoping review. PLoS ONE. 2017; 12: e0174847), representing 1.5M cases per year. Cognitive impairment includes symptoms such as short-term memory loss, trouble concentrating, difficulty multi-tasking, lack of focus, and slowed brain processing. We plan for ALPHA-1062 Intranasal to be studied in adult patients (18+ years) who are suffering from the cognitive symptoms associated with mild traumatic brain injury, with an addressable market of 1.1 million patients per year (3M diagnosed per year, 91% mild. 50% with cognitive impairment, 79% adults). We estimate that a treatment to manage cognitive impairment with mild TBI would have a $13.5B market size (1.1M cases per yr X assuming a $12.5K per treatment course) in the U.S. Due to high unmet need, no approved treatment, and disability associated with the disorder, there is a significant need for an approved treatment expressed by governments, payers, and physicians.

Our Products and Approaches to Treatment

The following table highlights our preclinical and clinical programs:



Alzheimer's Disease Mild-to-Moderate Stage: ALPHA-1062 prodrug, delayed release oral tablet

The Section 505(b)(2) regulatory approval pathway is a provision in the U.S. Federal Food, Drug, and Cosmetic Act. It allows a company to seek FDA approval for a drug product that contains previously approved active ingredients, but with new formulations, dosages, routes of administration, or indications. This pathway enables companies to rely on existing data, such as safety and efficacy information from studies on the previously approved drug, along with additional data to support the changes. It can offer a more streamlined and potentially faster route to market compared to traditional new drug applications.

A bioavailability and bioequivalence pivotal study is a type of clinical trial conducted to assess the pharmacokinetic properties of a drug formulation and its similarity to another formulation, typically a reference product. The primary objective of a bioavailability and bioequivalence study is to demonstrate that the test drug (e.g., a generic or modified formulation) is equivalent to a reference drug in terms of its

rate and extent of absorption into the bloodstream (bioavailability) and its subsequent distribution, metabolism, and excretion (pharmacokinetics). In contrast, traditional efficacy trials focus on demonstrating the clinical effectiveness and safety of a drug in treating a specific disease or condition.

The Company has filed an NDA using the 505(b)(2) pathway for approval. The Company has met with the FDA to discuss the regulatory requirements for a 505(b)(2) application, and has conducted its pivotal studies in direct alignment with the FDA feedback, as well as the FDA guidance document for 505(b)(2) approvals.

ALPHA-1062 is a patented new innovative product and 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 better patient outcomes. Drugs that convert from an inert form to an active substance in-situ are referred to as “prodrugs”. Since ALPHA-1062’s active moiety is galantamine, and because the Company is pursuing a 505(b)(2) pathway, the Company plans to leverage Galantamine’s efficacy data in promotion. At the time the Company licensed the ALPHA-1062 technology, only an intranasal formulation had been developed, and subsequently oral dosage formulations have been developed.

The Company believes ALPHA-1062 works in two different ways within the brain, by (1) raising the concentration of an essential chemical that transmits signals between nerve cells called acetylcholine, and (2) increasing the sensitivity of another chemical, called nicotinic acetylcholine receptors (nAChRs), which also enhances acetylcholine, regulates inflammation, defends against the loss of amyloid and strengthens other transmitters within the brain. The Company believes this results in enhancement and improvement of:

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

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

1) Clinical Development: Demonstrate, to the satisfaction of regulatory bodies, that ALPHA-1062 formulations have a significantly reduced side effect profile and differentiated mechanism of action from existing acetylcholinesterase inhibitor (AChEI) treatments, with the exception of galantamine’s mechanism of action.

2) Regulatory: Demonstrate that an NDA pathway called a 505(b)(2) is available for approval in the United States, allowing commercialization, that relies on the establishment of a scientific bridge to the findings of safety and efficacy of the FDA approved Razadyne utilizing a bioavailability and bioequivalence pivotal study instead of the traditional efficacy trials.

ALPHA-1062 sublingual formulation will be developed as an alternative formulation for patients who suffer from dysphagia (inability to swallow). A number of Alzheimer’s patients are estimated to suffer from dysphagia and utilize alternative liquid or patch formulations for medicine administration. A systematic review estimated dysphagia prevalence of greater than 80% of moderate to severe patients with Alzheimer’s. The sublingual formulation would allow for a dissolvable tablet that could provide medicine to these patients in an alternative method of administration. The Company completed an in vitro

study to evaluate absorption of the technology with a sublingual tablet formulation. The study demonstrated that the tablet enabled active drug release in 30 seconds. An open label, single-dose, bioavailability study was conducted to determine the plasma levels of ALPHA-1062 in healthy, adults under fasting conditions. An 11mg sublingual tablet was administered to 10 subjects to measure active bioavailability, tolerability, and safety. Study results demonstrated 90% bioavailability and a formulation that was well tolerated. No safety signals were observed in the study. The formulation is in early development phases. and further development will be contingent upon additional resources and alignment with Food and Drug Administration (FDA) regarding this development program.

Alzheimer's Disease Moderate-to-Severe Stage: ALPHA-1062 + Memantine Fixed Combination Drug

Should the Company receive approval for ALPHA-1062 for mild-to-moderate Alzheimer's Disease, we plan to progress the development of ALPHA-1062 + memantine. The product combination is currently in pre-clinical development phase and will require formulation work and potentially a preclinical study before submitting an IND to FDA. The Company plans to initiate the streamlined 505(b)2 regulatory path for approval, but will need additional FDA feedback on the required development steps for the combination asset. The Company believes ALPHA-1062 + memantine may utilize a triple mechanism of action approach to optimize therapeutic effect. The mechanism of action works via the dual ALPHA-1062 pathways, acetylcholinesterase inhibition and enhancing the nicotinic receptor activity and sensitivity, plus the memantine pathway via a different neurotransmitter called N-methyl-D-aspartate receptor antagonism (NMDA receptor). The Company believes ALPHA-1062 + memantine could potentially capture market share by providing education on its differentiating features and product profile to physicians who prescribe combination products, and to caregivers who care for patients already on a combination product and/or are in the later stages of Alzheimer's Disease symptom progression. The formulaton is in early development stages and further development will be contingent upon additional resources and further alignment with FDA on the development program.

Traumatic Brain Injury: ALPHA-1062 Intranasal Formulation

Mild Traumatic Brain Injury (mTBI): The Company has completed a pre-clinical study of ALPHA-1062IN in mTBI. The Company is encouraged by the preclinical data and met with the FDA in the second quarter of 2023 to discuss IND submission and gain alignment with FDA on further clinical plans. The FDA indicated in this meeting that further pre-clinical single species toxicity study and additional manufacturing work will be needed to file IND for Cognitive Impairment with mild Traumatic Brain Injury (mTBI) and potentially enter into a Phase 2 trial. The Company has completed Phase 1 clinical single ascending dose (SAD) and multiple ascending dose (MAD) studies with ALPHA-1062 Intranasal formulation for a different indication (Alzheimer's Disease) and believes these studies can be utilized with the mTBI indication because the formulation utilizes the same delivery system and active drug. The Company expects Alpha Seven will initiate the additional pre-clinical toxicity and manufacturing work which is anticipated to be completed by the end of 2024. Alpha Seven believes it would then be in the position to file an IND for ALPHA-1062IN. Further development work for ALPHA-1062IN will require additional resources which Alpha Seven Therapeutics does not currently have.

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-1062IN treated group was statistically indistinguishable from that of the uninjured cohort.

In a rodent model of TBI, ALPHA-1062IN 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-1062IN 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.

The Company completed single dose ascending study (SAD) with intranasal administration. The study was a double-blind, comparator and placebo-controlled, sequential cohort, single ascending dose study in 58 healthy subjects with ALPHA-1062IN in doses of 5.5, 11, 22, 33, 44mg compared with oral galantamine 16mg and donepezil 10mg. Safety, tolerability, pharmacokinetics, and pharmacodynamics were assessed. ALPHA-1062IN doses up to 33mg were well tolerated and induced a dose-dependent increase in plasma concentrations of ALPHA-1062IN and galantamine. ALPHA-1062IN was well tolerated and no safety issues were observed.

The Company completed multiple dose ascending study (MAD) with intranasal administration. The study was a randomized, double-blind, placebo-controlled study with multiple intranasal doses of ALPHA-1062IN in healthy subjects. Results from the study were ALPHA-1062IN plasma concentrations increased immediately following dosing, Cmax and AUC increased in a dose-linear manner over all three dose levels. ALPHA-1062IN adverse events were equivalent with placebo with no safety signals observed.

Our Strategy

The Company's principal business objectives are to:

1) obtain FDA approval for its NDA for ALPHA-1062 in mild-to-moderate Alzheimer's Disease. The Company has been granted a Prescription Drug User Fee Act (PDUFA) goal date of July 27th, 2024. The PDUFA date serves as a "best estimate" of when a decision on a New Drug Application would be forthcoming. This response may be a decision to approve the application or a Complete Response Letter (CRL). A CRL is a notice issued by the FDA indicating that an application will not be approved in its present form. Notwithstanding the goal date, the FDA could conduct a longer than expected regulatory review process, resulting in increased expected development costs or the delay or prevention of commercialization of ALPHA-1062. Even if ALPHA-1062 is ultimately approved, it may not achieve commercial success. The Company does not expect ALPHA-1062 to be commercially available immediately following approval. The Company will need to raise substantial additional capital in order to fund its operations and commercialization plans for ALPHA-1062, should the product be approved.

2) Continue to advance its development and commercialization activities for ALPHA-1062 in mild-to-moderate Alzheimer's Disease, including the commercial manufacturing for ALPHA-1062.

3) Pursue the out-licensing of its TBI indication to Alpha Seven, where the TBI indication can be further developed through a complete IND application submission following the completion of an additional toxicity study and formulation work. The NDA has been granted a Prescription Drug User Fee Act (PDUFA) goal date of July 27, 2024.

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

- ALPHA-1062 U.S. product approval for treatment of mild-to-moderate Alzheimer's Disease — The Company will need to respond to regulatory questions and inquiries from FDA in a satisfactory manner and negotiate the commercial label and approval of the product with FDA, which is anticipated in the third quarter of 2024. If approved, ALPHA-1062 would be the second oral therapy available for Alzheimer's patients in the past decade. The approval would represent a next generation oral treatment for disease that address the cognitive symptoms of Alzheimer's Disease. Approval could provide the Company with significant new business opportunities for commercial and/or development partners.

- Commercialization — The Company plans to continue its development activities and commercialization preparations around ALPHA-1062. CMC activities may involve continuing to refine and defining manufacturing practices and product specifications to be followed and met to ensure product safety and consistency between batches. This will include further CMC activities specifically to target commercial batches. The Company will also refine its commercialization marketing plan which includes the Long Term Care target market, prioritization of LTC customers, commercialization positioning, marketing messages, and operational plans.

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

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

Alzheimer's Disease Mild-to-Moderate Stage Program

Disease and Market Overview

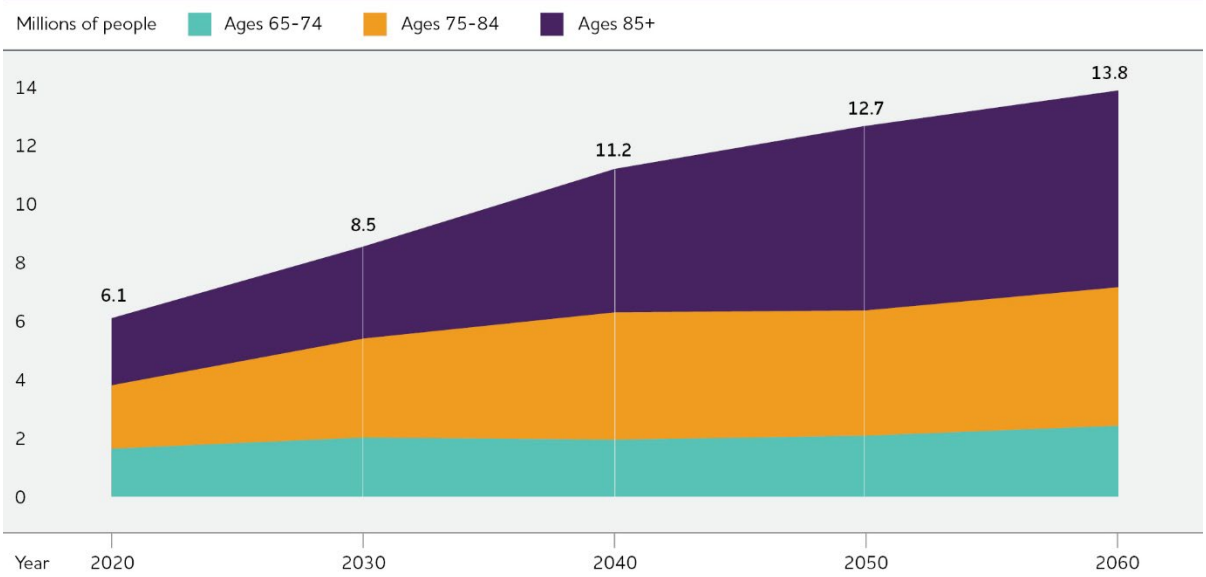
Alzheimer's Disease is the most common form of dementia and affects a large portion of the elderly population, approximately 6.7 million people in the United States 65 years or older. Alzheimer's Disease is a progressive disease of the brain which causes damage or destroys neurons in the section of the brain that controls cognition and functional ability, such as thinking, learning and memory.

The current and forecasted prevalence of Alzheimer's Disease is a large societal and public health care crisis. More than 1 in 9 elderly people have Alzheimer's Disease (age 65 or older), and of that group, 73% are actually 75+ years old with a majority (61%) being women. Alzheimer's Disease was officially listed as the sixth-leading cause of death in the United States in 2019. In 2020 and 2021, when COVID-19 became the third-leading cause of death, Alzheimer's Disease was the seventh-leading cause of death; official counts for 2022 are still being compiled. Though the length of time varies for each person, on average patients 65+ years will live for average four to eight years after their Alzheimer's Disease diagnosis. With the large baby boomer generation advancing in age and longer life expectancies, by 2025

Alzheimer's Disease prevalence is forecasted to rise 7% to 7.2 million people, and the number will jump to 13.8 million in the United Sates by 2060. Alzheimer's Disease is a significant societal and healthcare burden due to the large and growing at-risk patient population, physician perceived limited effectiveness of current treatments and a shortage of drug innovation.

Figure 5

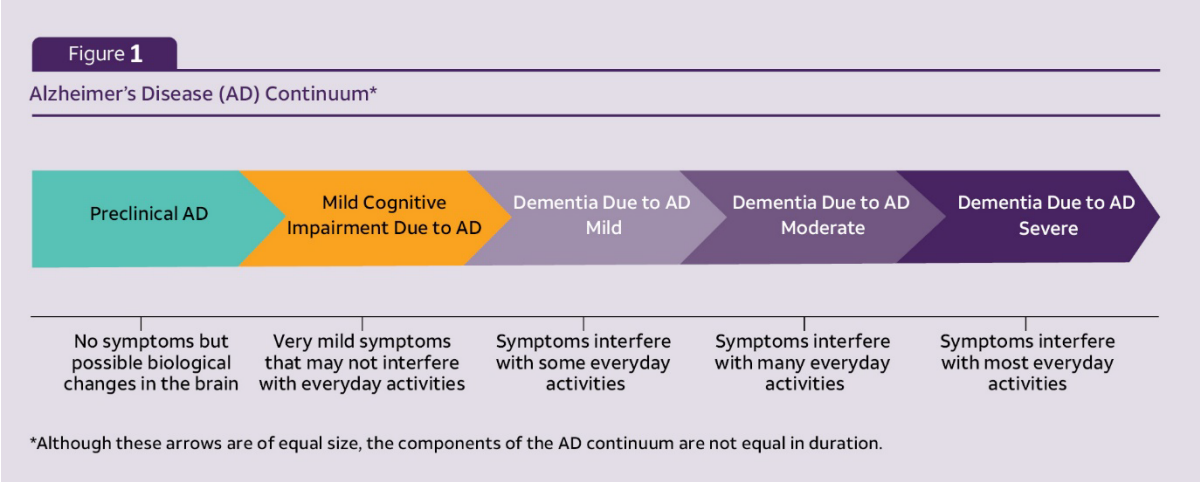
Projected Number of People Age 65 and Older (Total and by Age) in the U.S. Population with Alzheimer's Dementia, 2020 to 2060



Adapted from Alzheimer's Facts and Figures, 2023

Symptoms

here are 5 main stages of severity on the Alzheimer's Disease continuum, which are defined by brain changes and the resulting symptoms that affect a patient's daily life. These stages are preclinical Alzheimer's Disease, mild cognitive impairment (MCI) caused by Alzheimer's Disease, dementia due to mild Alzheimer's Disease, dementia due to moderate Alzheimer's Disease, and dementia due to severe Alzheimer's Disease. Alzheimer's Disease is believed to start causing changes in the brain upwards to 20 years prior to symptoms becoming noticeable. Within the brain, nerve cells become damaged and/or destroyed due to accumulation of beta-amyloid plaque clumps outside neurons, and the abnormal formation of tau tangles inside the neurons. As these brain changes become more prominent over the years, symptoms begin to occur and become noticeable. Common cognitive symptoms are memory loss, learning decline, challenges planning or solving problems, forming words/speaking and confusion with places or time. As symptoms become more severe, they affect daily activities, such as the ability going to the bathroom, eating and swallowing, drinking, and overall mobility. Alzheimer's Disease progresses within each person differently. Depending on the individual risk factors, time of diagnosis, and other factors, the length of time a patient is within each stage of the continuum will vary greatly.



Alzheimer's Disease symptoms affect the whole patient: mind, body and behavior/personality. The five main areas of symptoms are cognitive, psychological, physical, behavior, and other, which would include sleep disorder and rapid eye movement disorder.

Cognition	Psychological	Physical	Behavior	Other
Short term memory loss	Depression	Visual problems	Isolating/Withdrawal from work or social activities	Sleep disorder
Word-finding/communication difficulties	Mood disturbances	Writing	Disinhibition and impulsivity	Rapid eye movement disorder
Challenges planning – confusion with time and places	Apathy	Decreased ability to perform daily living activities: bathing, eating, drinking	Poor or decreased judgment	
Solving programs	Suspicion	Frequent falls		
Misplacing things	Anxious/fear			

Adapted from Porsteinsson 2021

An Alzheimer's Disease patient's diagnosis journey usually begins with their primary care physicians, as they are the first to detect cognitive impairment. Once detected, 99% of primary care physicians will refer the patient to a dementia specialist. Neurologists/Psychiatrists prescribe 27% of all Alzheimer's Disease Rxs and due to the large Alzheimer's Disease afflicted population within Long-Term Care (LTC) facilities, these physicians prescribe 36% of the total Rxs.

Alzheimer's Disease caregivers carry a heavy burden

People suffering from Alzheimer's Disease are not relegated only to the patients. Family members and caregivers are affected greatly and carry a huge burden due to this progressive disease. The vast majority (83%) of the 11 million unpaid Americans that provide care for Alzheimer's Disease patients are doing so for a family member, usually a parent or parent-in-law. Two-thirds are women and the majority are under the age of 65 years old. These caregivers provide upwards to 18 billion hours of unpaid care, which equates to $339.5 billion a year. While many believe they don't have the information or resources

necessary to do their job as a caregiver well, they feel they have no choice but to take on this role, as cited in a 2014 Alzheimer's Association pollIn addition to providing help with daily activities, caregivers are also providing emotional, physical, communication, and financial support. As the disease progresses and the patient exhibit behavioral and functional changes that are more severe, the burden becomes larger and the overall stress increases. According to the Alzheimer's Association, caregivers report feeling high emotional stress, and experience financial and physical difficulties while caring for their loved one.

Table 11

Percentage of Dementia Caregivers Who Report Having a Chronic Health Condition Compared with Caregivers of People without Dementia or Non-Caregivers

Condition	Dementia Caregivers	Non-Dementia Caregivers	Non-Caregivers
Stroke	5.2	3.4	3.2
Coronary heart disease	8.3	7.2	6.6
Cardiovascular disease*	11.8	9.5	8.6
Diabetes	12.8	11.1	11.3
Cancer	14.3	13.3	11.5
Obesity	32.7	34.6	29.5

*Combination of coronary heart disease and stroke.

Table includes caregivers age 18 and older.

Created from data from the Behavioral Risk Factor Surveillance System survey.[409]

Table includes caregivers age 18 and older

* Cardiovascular disease – combination of coronary heart disease and stroke

Adapted from Alzheimer's Association Facts & Figures 2023

Long-term care homes and death rates

Long-Term Care facilities carry a substantial burden in the care of Alzheimer's Disease patients. The costs of health care and long-term care for individuals with Alzheimer's or other dementias are substantial, and dementia is one of the costliest conditions to society. Researchers have estimated that approximately 75% of surviving Alzheimer's Disease patients diagnosed at age 70 will reside in a nursing home by age 80, compared with only 4% of the general population. 36% of short-stay (less than 100 days) nursing home residents have Alzheimer's or other dementias, and 58% of long-stay (100 days or longer) residents have this condition. Due to this large and growing population, 15% of nursing homes have a special dementia care unit, which the Company anticipates will become more common place over the coming years as more baby boomers are admitted. When a patient has been admitted into a long-term care facility, their Alzheimer's Disease symptoms are affecting daily activities and have caused general disability and overall decline in their health. The mental, emotional and physical stress on the caregiver and family members is extremely high. Some studies state distress remains unchanged or even increases after a relative is admitted to a residential care facility.

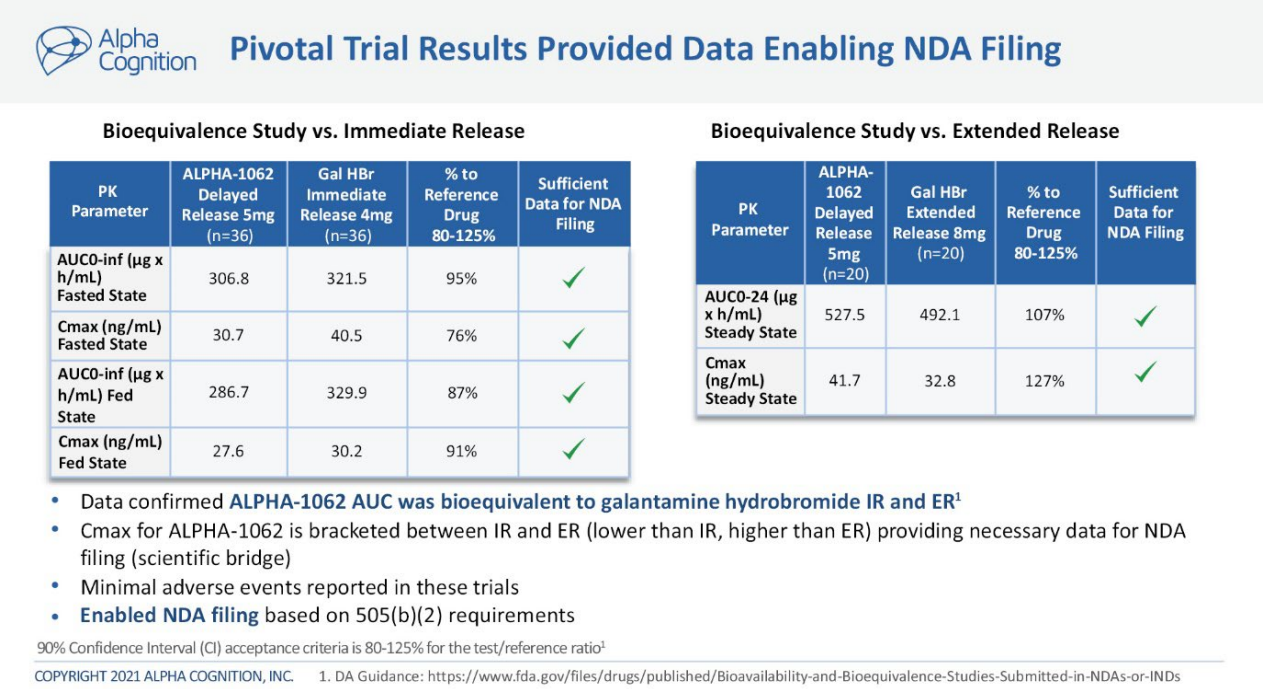
Alzheimer's Disease was officially listed as the sixth-leading cause of death in the United States in 2019.371 In 2020 and 2021, when COVID-19 became the third-leading cause of death, Alzheimer's Disease was the seventh-leading cause of death; official counts for 2022 are still being compiled. Alarmingly, deaths from Alzheimer's Disease have more than doubled from 2000 to 2019, to 145.2%, while all other major causes of deaths have declined or remained the same, such as cancer, heart disease or stroke. Alzheimer's Disease accounts for two-thirds of deaths in a nursing home, which is greater than cancer and any other condition. Due to the stress associated with caring for a loved one suffering from Alzheimer's Disease, 72% of family caregivers experienced relief when the person with Alzheimer's or another dementia died.

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 Trials: The Company completed two studies in the second quarter of 2022 and a third study in the third quarter of 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. The studies were designed in accordance with FDA 505b2 guidance for industry All studies were completed with Vimta Labs, Inc. in India, a clinical research organization with significant experience in running bioanalytical and bioequivalence studies. Primary endpoints of all studies were to evaluate bioavailability and bioequivalence by comparative measurements of peak plasma concentration (Cmax), and area under the plasma concentration-time curve from time zero to infinity (AUC0-inf.). Secondary endpoints were to measure adverse events and safety outcomes. Topline results confirmed in bioequivalence studies that ALPHA-1062 achieved bioequivalent area-under-the-curve (fed and fasted) and peak exposures (fed) relative to galantamine hydrobromide immediate release and galantamine hydrobromide extended release. There were minimal adverse events (<3%) reported for ALPHA-1062 during these studies. With these positive pivotal study results, the Company filed an NDA for ALPHA-1062 in mild to moderate Alzheimer's Disease during the third quarter of 2023, with possible FDA approval for the U.S. market by the third quarter of 2024.

The following table summarizes the results of the ALPHA-1062 Pivotal Study Bioequivalence/ Bioavailability ("**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

The primary objective of both the fed and fasted studies was to evaluate the relative bioavailability of a single-dose of oral ALPHA-1062 (or galantamine benzoate) 5mg delayed release tablet compared to galantamine hydrobromide tablet 4mg immediate release — the reference drug. Primary endpoints of these studies were to evaluate bioavailability and bioequivalence by comparative measurements of peak plasma concentration (Cmax), and area under the plasma concentration-time curve from time zero to infinity (AUC0-inf.). Secondary endpoints were to measure adverse events and safety outcomes. 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 AUC0-inf or area under the curve, and Cmax, the highest concentration of drug in the blood. The area under the curve represents the total exposure to the active drug galantamine over time after a single administration, and the Cmax represents the highest peak exposure to galantamine.

Bioequivalence of ALPHA-1062 to galantamine hydrobromide was established in both the fed and fasted studies with the 90% confidence intervals for area under the curve falling within the 80%-125% bioequivalence range. The mean area under the curve ratio to reference drug for ALPHA-1062 was 95% (306.8) in the fasted study and 87% (286.7) in the fed study.

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

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

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 oral ALPHA-1062 5mg 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 Cmax was expectedly higher than that of the extended release reference. These data, coupled with the positive pivotal data released in June, establish bioequivalence to both formulations of galantamine hydrobromide and strengthen the NDA application for ALPHA-1062 in mild-to-moderate Alzheimer's Disease, filed in the third quarter of 2023. The Company prepared and filed the NDA with the FDA and the file is pending FDA review and approval

The study was a two-treatment, two-period, crossover study wherein 40 subjects were randomly assigned 1:1 to either treatment with ALPHA-1062 5mg twice daily, or galantamine hydrobromide 8mg extended release 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. Primary endpoints of all studies were to evaluate at day seven bioavailability and bioequivalence by comparative measurements of peak plasma concentration of test and reference (Cmax), and area under the plasma concentration-time curve from time zero to infinity (AUC0-24.). Secondary endpoints were to measure adverse events and safety outcomes.

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 (Cmax) of approximately 107% and 127%, respectively, compared to those generated by galantamine hydrobromide extended release. As expected, Cmax 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 the 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.

Multiple dose administration of ALPHA-1062 was well tolerated with two adverse events reported, both of which were mild and transitory. No serious safety issues were observed in the study. 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. Labeling and manufacturing guidance for stability of ALPHA-1062 was provided by FDA to support commercial strengths in commercially marketed product. The Company has since demonstrated required stability endpoints for twelve months of long-term stability data in the three

to-be-marketed strengths of ALPHA-1062. The RESOLVE trial was a trial designed to measure adverse events in an Alzheimer's population and provide label enabling data for ALPHA-1062. It was not a required trial to complete in order to submit an NDA application for approval. Post second quarter meeting with FDA, the Company determined this trial would not be implemented and informed the FDA on this matter. As a result of the agency's feedback, the Company filed its NDA for ALPHA-1062 in mild-to-moderate Alzheimer's Disease in the third quarter of 2023, allowing the Company to include additional CMC stability data in the NDA filing. The Company's Prescription Drug User Fee Act (PDUFA) date for ALPHA-1062 is July 27, 2024.

ALPHA-1062 Alzheimer's Disease Commercialization Strategy

During the second half of 2023 the Company started, in parallel with the Company's regulatory activities, taking steps to develop a commercialization team to launch ALPHA-1062 in the U.S. The Company has completed sufficient planning to indicate that ALPHA-1062 could be launched using a specialty sales force that will focus on Long Term Care (LTC) physicians in the U.S. Long term care physicians who treat elderly patients that reside in nursing homes also make pharmacologic decisions in concert with the LTC treatment team. Our research has indicated that the acetylcholinesterase inhibitor (AChEI) prescription market in the U.S. from the LTC market is large, representing 36% of the over 11 million prescriptions filled in pharmacies each year. The AChEI class includes Aricept, Exelon, Exelon Patch, Razadyne, Adlarity, Namzaric, and generic versions of the AChEIs. Prescription data suggests that there is currently high turnover of patients treated with currently approved AChEI medications, with 30% of patients discontinuing treatment by month 4 and 55% discontinuing treatment within one year. The Company believes that patients who discontinue a first therapy will try a 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. The Company will attempt to secure product coverage with U.S. payors. Market research indicates that payors are likely to cover ALPHA-1062 if the product is competitively priced.

Additionally, the Company intends to seek strategic partnerships to expand promotional efforts and physician promotional coverage. As ALPHA-1062 nears FDA regulatory approval, the Company will seek distribution partners for major territories, identified as Europe, LATAM (Mexico, Central and South America), and Asia. Distributors often have a deep understanding of local market dynamics, including regulatory requirements, distribution channels, and consumer preferences. Partnering with a local distributor should allow the Company to leverage this expertise and navigate the complexities of entering a new market more effectively. FDA regulatory approval does not guarantee regulatory approval for distribution in other territories. We will need to seek and obtain regulatory approval through the processes in each of the above mentioned jurisdictions, which will take additional time and resource. Please see "*Risk Factors — We have conducted, and in the future plan to conduct, clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials*". Additionally, the Company intends to seek approval for potential additional indications and product line extensions.

Potential ALPHA-1062 coverage and reimbursement in the United States

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

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

Our solution: ALPHA-1062

There is a significant unmet need for better treatment options for patients suffering from Alzheimer's Disease. The Company believes that ALPHA-1062 is poised to be a next-generation treatment option. The Company believes that we can differentiate ALPHA-1062 based on several potential advantages to Alzheimer's Disease patients:

- efficacious cognitive and functional improvement results
- clinical data published in Neurology in April 2021, supports significant risk reduction in risk of developing severe dementia and strongest effect on cognition
- dual mechanism of action, enhancing the acetylcholine levels and nicotinic receptor sensitivity
- enteric-coated tablet that bypass the GI as an inactive compound to potentially minimize GI side effects (nausea, vomiting, and diarrhea)
- no incidence of insomnia

According to third-party market research conducted by Infinity Group in October 2021, market research confirms that based on the product attributes listed above, 88% of LTC prescribers are likely to prescribe ALPHA-1062, with a 29% preference share.

Alzheimer's Disease Moderate-To-Severe Stage Program

Disease and Market Overview

Our second program is a combination oral product for moderate-to-severe Alzheimer's Disease. The product is in formulation and pre-clinical development. The Company believes combining ALPHA-1062 with previous FDA approved NMDA receptor memantine would provide differentiating efficacy and an attractive tolerability profile to patients within these advance stages. Moderate Alzheimer's Disease and severe Alzheimer's Disease affects a total of ~1.4M patients in the United States. In 2020, over 7 million Rx's were written for the memantine-containing product. In the moderate stage of Alzheimer's Disease symptoms becomes more intense, significantly affecting their everyday life. They have difficulties with communication and personality and behavioral changes present. The caregiver burden also increases during this stage, as many activities (dressing, bathing, bathroom) require assistance and management. In the severe stage of the disease, patients will experience more robust and debilitating symptoms. The complete deterioration of cognition and functional abilities require round-the-clock care, eating and drinking prove difficult, and they usually become bed bound. On average 40% of the final years of an Alzheimer's Disease patients (ages 70 to 80 years old) will be spent in the severe stage and the nature of the symptoms leads to the vast majority being admitted into a Long-Term Care facility.

Increasing caregiver burden

The caregiver burden rises to new heights during these stages, and many describe it as “extremely stressful”. The last 12 months of life, people with dementia relied on more hours of family care (64.5 hours per week), 59% of caregivers felt they were “on duty” 24 hours a day, and financial care costs increase. Once a decision is made to place the patient into a Long-Term Care facility, the stress of the caregiver isn’t alleviated. In fact, many say the distress is unchanged or even increases.

Our Product and Approach to Treatment

The Company plans to develop ALPHA-1062+ Memantine, a combination of ALPHA-1062 and Namenda XR, to simplify the co-administration of these drugs by a patient or caregiver with the goal of increasing compliance and adherence to the prescribed regimen. We believe that ALPHA-1062 + Memantine has the potential to be adopted by patients already taking Namzaric® or generic combination therapy as well as moderate to severely affected patients currently taking donepezil or memantine alone.
Should the Company receive approval for ALPHA-1062 for the treatment of mild-to-moderate dementia associated with Alzheimer’s Disease, it plans to progress the development of ALPHA-1062 + memantine through a streamlined 505(b)2 regulatory path. The product combination is currently in a pre-clinical stage of development and will require additional product development and pre-clinical studies to advance to an IND. Should the product advance ultimately to FDA approval, the Company believes ALPHA-1062 + memantine would have the potential to provide differentiating product characteristics including, 3 mechanisms of action and a minimal side effect profile for the treatment of moderate-to-severe dementia associated with Alzheimer’s Disease. The Company believes ALPHA-1062 & memantine will be absorbed through the gastrointestinal tract; ALPHA-1062 inertly with minimal gastrointestinal side effects and memantine with acceptable side effects when up-titrated. The combination therapy will act via 3 distinct mechanisms of action acetylcholinesterase inhibition, enhanced nicotinic receptor activity and sensitivity, and NMDA receptor antagonism. The Company believes ALPHA-1062 + memantine could capture substantial market share due to physicians’ established practice of prescribing combination therapies in later stages of Alzheimer’s Disease and patients’ acceptance of multiple medications.

As long-term care settings predominate in the provision of care to moderately-to-severely affected patients, the Company will also raise awareness of the compelling results from the Swedish Dementia Registry that demonstrated that galantamine had the strongest effect on cognitive improvement and was the only drug to demonstrate a significant reduction in the risk of developing severe dementia, and a lower risk of death as compared to other evaluated acetylcholinesterase inhibitors.

Should both ALPHA-1062 and the combination therapy (ALPHA-1062+Memantine) ultimately be approved for commercialization, the Company would be able to offer a solution that treats all the stages of Alzheimer’s Disease. The Company will plan to leverage the existing sales forces established for the mild-to-moderate indication targeting Long-Term Care providers. These groups make up 36% of all Rx within the Alzheimer’s Disease market. The Company will promote awareness and educate on differentiating features of its marketed treatments The sales force approach will consist of long-term care home materials, peer-to-peer learning programs, partnerships with Alzheimer’s Disease and long-term care societies and associations.

For caregivers, we plan to deploy a targeted multi-channel market campaign with the goal of motivating requests for ALPHA-1062 + memantine from their physician. Channels utilized will be focused on long-term care home, partnership with patient advocacy groups, public relation efforts, website education, and a focused media strategy.

Potential ALPHA-1062 coverage and reimbursement in the United States

U.S. payers have granted branded Namzaric® wide access to most MA-covered lives and it is mostly covered on preferred tiers. The Company believes the ALPHA-1062 + memantine would be treated similarly. Should ALPHA-1062 receive approval for mild-to-moderate Alzheimer's Disease, the payer team intends glean additional insights from their customers to determine commercial price and potential payer coverage by the payer community.

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 and ALPHA-1062 Positioning

Alzheimer's Disease symptomatic treatments are currently limited and perceived to provide limited symptom improvement and cause difficult to manage tolerability side effects. Symptomatic treatments are designed to improve the ability to learn, remember key events and loved ones, and function normally with daily tasks like toileting, cooking, or home care. Each year greater than 2 million patients are on medication for the disease, which makes up half of the estimated number of people with Alzheimer's Disease in the 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.

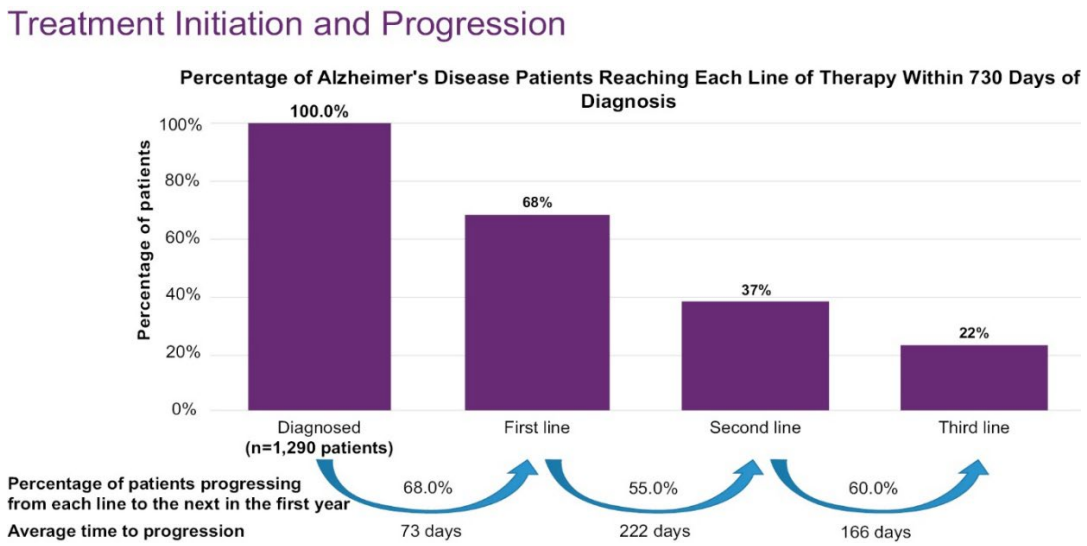
There are four symptomatic drug treatments that have been approved by the FDA to date for mild to moderate Alzheimer's Disease.

(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 extended release 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 Easai) 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 overage, it is not easily accessible and will only be covered for qualified clinical trial patients. Leqembi is indicated for the treatment of Alzheimer's Disease. It is expected that coverage and utilization may be better for Leqembi than Adulhelm, but this will only be apparent after several quarters of commercialization. It is important to note that DMT agents will not be a competitor to the current standard of care, the AChEI class. DMTs will be used in combination with these medications, as they do not address the symptoms of the disease.

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



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), insomnia, cause a substantial rate of treatment discontinuation. Some data and studies suggest that patients on acetylcholinesterase inhibitor medications, will discontinue treatment approximately 30% of the time within 4 months and 55% discontinue therapy within 12 months. Gastrointestinal issues are cited as a leading reason for discontinuing treatment, as reported in both physicians and caregiver market research. The high rates of gastrointestinal adverse effects are also included in the prescribing information for each approved drug. The most common adverse events that are reported to lead to discontinuation of therapy were diarrhea, nausea, vomiting, dizziness and decreased appetite among acetylcholinesterase inhibitors. Prescribing habits within long-term care physicians, seem to be well entrenched, and overall, physicians report feeling dissatisfied and/or apathetic about their symptomatic treatment options. Caregivers also expresses dissatisfaction with the currently approved symptomatic treatments options.

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 expand on the original therapeutic use patent. The Company intends to patent all commercially relevant forms, formulations and routes/methods of ALPHA-1062 delivery in order to extend the effective patent protection lifetime. Effective patent protection of ALPHA-1062 and therapeutically relevant salts, polymorphs and/or formulations thereof may potentially be extended beyond 2042.

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).

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

In Europe, 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 granted 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 US 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).

Jurisdiction	Patent number	Status	Expiry Date
Australia	AU 2013294917	Granted	07/2033
Europe (11, and 18, European Patent Convention member states)	EP 2877165 EP 3417862	Granted Granted Divisional	07/2033
Japan	JP 6574002 JP 6799648	Granted Granted Divisional	07/2033
Canada	CA 2,878,135	Granted	07/2033
United States	US 11,077,119 US 16,287,413	Granted 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 WO2022236396).

Jurisdiction	Patent number	Status	Expiry Date
Australia	2021445637	Pending	05/2041
Canada	3,218,929	Pending	05/2041
China	2021800981674	Pending	05/2041
Hong Kong	n/a	Pending	05/2041
Europe	21941020.6	Pending	05/2041
Japan	2023-570185	Pending	05/2041
United States	18/560,636	Pending	05/2041

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 (PCT application WO2022150917).

Jurisdiction	Patent number	Status	Expiry Date
United States	US 11,795,176 18/463157	Granted Pending Continuation	01/2042
Europe	21152317.0 22738869.1	Priority Pending Pending	01/2042
Singapore	11202304626U	Pending	01/2042
Russia	2023121087	Pending	01/2042
Mexico	MX/a/2023/008276	Pending	01/2042
Korea	10-2023-7024970	Pending	01/2042
Japan	2023-565641	Pending	01/2042
Israel	303907	Pending	01/2042
China	2022800098271	Pending	01/2042
Hong Kong	62024086161.2	Pending	01/2042
Canada	3,205,859	Pending	01/2042
Brazil	BR 11 2023 013926 0	Pending	01/2042
Australia	2022208641	Pending	01/2042

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. The USPTO granted a patent on October 24, 2023, which issued as US 11,795,176.

Blood Brain Barrier VI (BBB VI): ALPHA-1062 for Treating Traumatic Brain Injury (TBI)

Jurisdiction	Patent number	Status	Expiry Date
PCT application	WO2023092231	Pending	est. 2042
United States	18/549,309	Pending	

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 ALPHA 1062. The European priority application remains pending. The international PCT-application is pending, and national phases are to be elected in May 2024. The U.S. national phase has already been initiated and remains pending.

Blood Brain Barrier VII (BBB VII): ALPHA-1062 for Treating Post Concussive Syndrome (PCS)

Jurisdiction	Patent number	Status	Expiry Date
US provisional	63/504292	Priority filing, PCT intended (not published)	est. 2043

This invention is based on treating cognitive impairment in patients with persistent post-concussion symptoms (PCS) after TBI, using ALPHA 1062. A U.S. provisional application was filed May 25, 2023. An international PCT application is planned in May 2024.

Blood Brain Barrier VIII (BBB VIII): Coated tablets for pH-dependent release of benzgalantamine

Jurisdiction	Patent number	Status	Expiry Date
United States	18/434155	Priority filing, PCT intended (not published)	est. 2045

Employees and Human Capital Resources

The Company has 4 full-time employees and 1 part time contractors in total. Employees and contractors work virtually and in offices located in Vancouver (British Columbia), West Palm Beach (Florida), and Dallas/Fort Worth (Texas). 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, 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.

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 bioavailability and bioequivalence (BABE) clinical trials. Based on historical experience of these CROs, including independent third party audits and monitoring commissioned by the Company at these sites, the Company believes that the CROs and sites meet international and FDA standards required to conduct Pilot and 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. Distributors often have a deep understanding of local market dynamics, including regulatory requirements, distribution channels, and consumer preferences. Partnering with a local distributor allows pharmaceutical companies to leverage this expertise and navigate the complexities of entering a new market more effectively. By outsourcing distribution activities to a reliable partner, the Company can focus our resources and expertise on our core competencies, such as commercializing in the U.S. FDA regulatory approval does not guarantee approval and/or distribution in other 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 innovative product 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 7½ 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. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates 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 inseverable 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, such efforts 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". 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. 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.

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.sedarplus.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 April 30, 2024, there were 150,175,536 Common Shares issued and outstanding and 7,916,380 Preferred Shares issued and outstanding. There are no Restricted Shares issued and outstanding. There are options outstanding to purchase up to 20,399,367 Common Shares at exercise prices ranging from C$0.22 to US$0.40. There are warrants outstanding to purchase up to 61,482,886 Common Shares at exercise prices ranging from US$0.283 to US$0.40. There are performance shares outstanding to purchase up to 6,821,057 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 issued Restricted Shares 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. On August 29, 2023, the Company converted all 7,000,000

outstanding Restricted Shares to Common Shares by resolution of the Board. There are currently no Restricted Shares issued and outstanding. The class of Restricted Shares differs 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 may 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 Shares 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 April 30, 2024, the Company had 61,482,886 warrants to purchase Common Shares of the Company outstanding as follows:

Date of Issuance	Number Issued	Exercise Price	Expiry Date
January 19, 2024	18,003,092	US$0.31	January 19, 2027
December 22, 2023	9,864,305	US$0.31	December 22, 2026
November 8, 2023	2,524,993	US$0.31	November 8, 2026
October 16, 2023	876,595	US$0.31	October 16, 2026
August 31, 2023	3,329,828	US$0.31	August 31, 2026
March 15, 2023	719,904	C$0.39	March 15, 2028
March 15, 2023	6,557,165	US$0.283	March 15, 2028
February 16, 2023	2,155,000	C$0.39	February 16, 2028
February 16, 2023	14,640,221	US0.289	February 16, 2028
March 18, 2021	2,811,783	US$0.40	August 30, 2024

Stock Options

As at April 30, 2024, the Company had 20,399,367 stock options to purchase Common Shares outstanding as follows:

Date of Issuance	Number Issued	Exercise Price	Expiry Date
June 8, 2023	15,858,559	C$0.22	June 8, 2033
January 18, 2023	450,000	C$0.28	May 31, 2032
January 18, 2023	257,500	C$0.28	April 11, 2032
January 18, 2023	215,000	C$0.28	February 14, 2032
January 18, 2023	940,000	C$0.28	December 20, 2031
January 18, 2023	2,600,000	C$0.28	August 3, 2031
March 18, 2021	39,154	US$0.40	July 22, 2030
March 18, 2021	39,154	US$0.40	June 1, 2029

Performance Shares

As at April 30, 2024, the Company had 6,821,057 performance shares to purchase Common Shares outstanding as follows:

Date of Issuance	Number Issued	Exercise Price	Expiry Date
March 18, 2021	2,000,000	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	180,000	US$0.01	June 30, 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 and the CSE on a monthly basis for the financial year ended December 31, 2023:

Month	High (C$)	Low (C$)	Volume
December 2023	$0.99	$0.30	481,540
November 2023	$0.39	$0.23	102,715
October 2023	$0.46	$0.30	186,705
September 2023	$0.44	$0.34	246,602
August 2023	$0.48	$0.32	1,003,064
July 2023	$0.44	$0.24	698,143
June 2023	$0.29	$0.19	301,137
May 2023	$0.26	$0.20	185,428
April 2023	$0.26	$0.22	217,368
March 2023	$0.49	$0.21	629,982
February 2023	$0.44	$0.29	71,031
January 2023	$0.47	$0.28	95,583

The Listed Warrants were traded on the CSE under the symbol "ACOG.WT". Prior to May 1, 2023, the Listed Warrants were traded 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 and the CSE on a monthly basis for the financial year ended December 31, 2023:

Month	High (C$)	Low (C$)	Volume
December 2023	n/a	n/a	n/a
November 2023	n/a	n/a	n/a
October 2023[(1)]	$0.01	$0.01	0
September 2023	$0.01	$0.01	0
August 2023	$0.01	$0.01	0
July 2023	$0.01	$0.01	0
June 2023	$0.01	$0.01	100
May 2023	$0.01	$0.01	0
April 2023	$0.01	$0.01	0
March 2023	$0.01	$0.01	0
February 2023	$0.01	$0.01	20,000
January 2023	$0.01	$0.01	0

Notes:

(1) The Listed Warrants expired on October 1, 2023.

Prior Sales

During the most recently completed financial year the Company issued the following securities that are outstanding, but not listed or quoted on a marketplace:

Type of Securities	Date of issue or grant	Number of Securities	Issue or Exercise Price of Security	Expiry date
Warrants	December 22, 2023	9,864,305	US$0.31	December 22, 2026
Warrants	November 8, 2023	2,524,993	US$0.31	November 8, 2026
Warrants	October 16, 2023	876,595	US$0.31	October 16, 2026
Warrants	August 31, 2023	3,329,828	US$0.31	August 31, 2026
Stock Options	June 8, 2023	15,858,559	C$0.22	June 8, 2033
Stock Options	January 18, 2023	450,000	C$0.28	May 31, 2032
Stock Options	January 18, 2023	257,500	C$0.28	April 11, 2032
Stock Options	January 18, 2023	215,000	C$0.28	February 14, 2032
Stock Options	January 18, 2023	940,000	C$0.28	December 20, 2031
Stock Options	January 18, 2023	2,600,000	C$0.28	August 3, 2031

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 as at the Company's most recently completed financial year. As of March 29, 2024, all securities listed below were released from escrow.

Designation of Class	Number of securities held in escrow or that are subject to a contractual restriction on transfer	Percentage of Class
Common Shares	12,702,874[(1)(2)(3)]	10.75%
Preferred Shares	2,857,432[(4)]	36.1%
Performance Shares	2,645,927[(5)]	38.97%
Warrants	289,600[(6)]	<1%

Notes:

(1) 10,297,749 Common Shares were subject to the Escrow Agreement.

(2) 93,279 Common Shares were subject to the CPC Escrow Agreement.

(3) 2,311,846 Common Shares were subject to the TSX-V seed share resale restrictions (the "**Seed Share Resale Restrictions**").

(4) 2,592,472 Preferred Shares were subject to the Escrow Agreement. 264,960 Preferred Shares were subject to the Seed Share Resale Restrictions.

(5) 2,596,427 performance shares were subject to the Escrow Agreement. 49,500 performance shares were subject to the Seed Share Resale Restrictions.

(6) Subject to the Escrow Agreement.

Escrow Agreement

Pursuant to the terms of the Escrow Agreement, the securities were 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 were 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
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 were 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 directors are elected annually and, unless re-elected, retire from office at the end of the next annual general meeting of shareholders. As a group, the directors and executive officers beneficially own, or control or direct, directly or indirectly, a total of 20,602,774 Common Shares, representing approximately 13.72% of the Common Shares outstanding as at the date of this AIF, and a total of 4,604,380 Preferred Shares, representing approximately 58.16% of the Preferred Shares outstanding as at the date of this AIF.

The following table sets out the names of the current directors and executive officers of the Company as at the end of the Company's most recently completed year ended December 31, 2023, 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 Preferred Shares, and percentage of the issued Common Shares and Preferred Shares, beneficially owned, directly or indirectly, or subject to control or direction by that person.

Name, Position and Municipality of Residence	Principal Occupation for the Past Five Years[(1)]	Director/ Executive Officer Since	Number and Percentage of Voting Securities Beneficially Owned or Controlled[(2)]
Michael McFadden Texas, United States *CEO and Director*	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	288,348 Common Shares <1%
Don Kalkofen Texas, United States *CFO*	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	367,500 Common Shares <1%
Lauren D'Angelo California, United States *COO*	Ms. D'Angelo's principal occupation is acting as the COO of the Company. Previously, Ms. D'Angelo served as Vice President, Marketing and Commercial Strategy at Urovant Sciences.	May 4, 2021	Nil
Kenneth Cawkell New Westminster, British Columbia *Corporate Secretary and Director*	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	5,461,899 Common Shares 3.57% 2,000,000 Preferred Shares 25.26%

Name, Position and Municipality of Residence	Principal Occupation for the Past Five Years[1]	Director/ Executive Officer Since	Number and Percentage of Voting Securities Beneficially Owned or Controlled[2]
Len Mertz[3][5] Texas, United States *Chairman and Director*	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 Mertzon.	March 18, 2021	5,588,134 Common Shares 3.72% 1,500,380 Preferred Shares 18.95%
John Havens[3][5] Texas, United States *Director*	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	7,030,988 Common Shares 4.68%
Phillip Mertz[4] Virginia, United States *Director*	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	1,569,826 Common Shares 1.05% 1,104,000 Preferred Shares 13.95%
Rajeev 'Rob' Bakshi[3][4] White Rock, British Columbia *Director*	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 Alpha Seven, 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 Len Mertz (independent), Rajeev 'Rob' Bakshi (independent) and John Havens (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

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 Mertzon. 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 as 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 is an accomplished real estate and technology investor and advises both private and public companies.

John Havens – Since 1978, Mr. Havens has been the President of Seismic Exchange, Inc. Mr. Havens also has a long history as an entrepreneur as both a founder and significant investor in various industries, with a focus on growth through vertical integration and strategic acquisitions. He has served as Vice Chairman/Board Member of the Houston Astros and as an active member of numerous other business and community boards.

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:

Financial Year Ending	Audit Fees	Audit Related Fees	Tax Fees	All Other Fees
December 31, 2023	$175,000	$92,500	Nil	Nil
December 31, 2022	$110,000	$124,975	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, 2023, 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, 3rd 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, 2023, 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. 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.

8. A Third Amended License Agreement effective dated April 1, 2024, 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.sedarplus.com.

Additional financial information is provided in the Company's audited financial statements and Annual MD&A for the year ended December 31, 2023.

Copies of the Company's financial statements and Annual MD&A may be obtained upon request from the Company's office by mail to 1200 – 750 West Pender Street, Vancouver, British Columbia, V6C 2T8, or may be viewed on SEDAR+ at www.sedarplus.com.

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 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. At all times while the Company has listed its common shares on the Nasdaq Stock Market, 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

The Committee shall:

a) 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.

b) 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.

c) 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.

d) Review and approve the independent auditors' annual engagement letter.

e) 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.

f) 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.

g) 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.

h) 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.

i) Review and satisfy itself on behalf of the Board with respect to the Company's internal control over financial reporting and information systems.

j) 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.

k) Review and approve all related-party transactions of the Company.

l) 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).

m) Inquire of management and the independent auditor about significant business, political, financial and control risks or exposure to such risk.

n) 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.

o) Assess the effectiveness of the over-all process for identifying principal business risks and report thereon to the Board.

p) 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.

SCHEDULE "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.
c/o 1200-750 West Pender Street
Vancouver, BC V6C 2T8
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 securities of the Company. 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 U.S. 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. 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.

Risks Related to Our Financial Condition

We are a clinical-stage/pre-commercial biopharmaceutical company in the late stages of development with no products approved for commercial sale and have incurred significant losses since our inception. We expect to incur significant losses 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 $18.2 million for the years ended December 31, 2023, and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $63.3 million. We have also raised gross proceeds of $12.9 million through our private placements during 2023 and in to January 2024. 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 over the next several years. We expect that it could be several years, if ever, before we have a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially for the foreseeable future as we will be:

- conducting our ongoing and planned clinical trials of ALPHA-1062, as well as our plans to initiate and complete additional clinical trials;

- pursuing regulatory approval of ALPHA-1062 for the treatment of mild-to-moderate Alzheimer's Disease;
- continuing our clinical validation of ALPHA-1062 for moderate-to-severe Alzheimer's Disease and exploring the potential related to mTBI;
- 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;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- incur additional legal, accounting and other expenses in operating as a public company; and
- scale up our clinical and regulatory capabilities.

There is substantial doubt about our ability to continue as a going concern.

Due to our ongoing net losses, there is substantial doubt about our ability to continue as a going concern. As a result, management has included disclosures in Note 1 of our financial statements and our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements for the fiscal year ended December 31, 2023, with respect to this uncertainty. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities and to raise additional capital to finance our operations.

There is no assurance that we will succeed in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

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 date, we have not generated any revenue from the commercialization of our product candidates. 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 the NDA submission of ALPHA-1062 for the treatment of mild-to-moderate 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. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a limited operating history, have not yet completed an Alzheimer's Disease patient tolerability study for ALPHA-1062 and have no history of commercializing products, 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 our operations to date have been largely focused on developing our clinical and preclinical product candidates, primarily ALPHA-1062. 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, or conduct sales and marketing activities necessary for successful commercialization. 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 or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We may also need to transition from a company with a research focus to a company capable of supporting commercial activities. Our inability to adequately address these risks and difficulties or successfully make such a transition could adversely affect our business, financial condition, results of operations and growth prospects.

We will need substantial additional 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. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for the foreseeable future, if at all. If we obtain marketing approval for ALPHA-1062 or any other product candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company.

As of December 31, 2023, we had $1.4 million in unrestricted cash and cash equivalents and have not generated positive cash flows from operations. Based on our current business plans, we believe our existing cash and cash equivalents, and the gross capital raised from through January 2024 of $3.7 million, will not be sufficient for us to fund our ongoing operating expenses, pre-NDA approval commercialization expenses, and capital expenditures requirements through at least the next 12 months, and that additional capital will need to be raised to fund our operations and commercial plans. Prior to and or following the NDA approval for ALPHA-1062 in Alzheimer's Disease, if obtained, we expect to proceed with our full commercial launch of the product, where we would expect to raise substantial additional capital to continue our commercialization efforts and bring the product to market in the U.S. We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, progress, costs and results of our ongoing support of ALPHA-1062 and the NDA, as well as the associated costs, including any unforeseen costs we may incur as a result of additional preclinical study or clinical trials that may be required, or other delays;
- the scope, progress, costs and results of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs we advance them through preclinical and clinical development;
- the number and development requirements of other product candidates that we may pursue;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the effect of competing products that may limit market penetration of our products;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize ALPHA-1062 or any of our other product candidates outside the United States;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products, or technologies; and
- the additional costs we may incur as a result of operating as a public company, including our efforts to enhance operational systems and hire additional personnel, including enhanced internal controls over financial reporting.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The Company expects to need to raise additional capital since our current available funds will not be sufficient to fully fund our planned pre-commercial and commercial efforts should we receive FDA approval for ALPHA-1062 in Alzheimer's Disease. Following the NDA approval for ALPHA-1062 in Alzheimer's Disease, if obtained, we expect to proceed with our full commercial launch of the product, where we expect to raise substantial additional capital to continue our commercialization efforts and bring the product to market in the U.S. and continue development of our product candidates. We expect to incur significant commercialization expenses related to product manufacturing, sales, marketing, distribution, and continued research and development.

We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Additional funds 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 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

We expect to be exposed to fluctuations in currency exchange rates, which could adversely affect our results of operations.

We incur expenses in U.S. dollars, Canadian dollars, and EUROs but our financial statements are denominated in U.S. dollars. Accordingly, we face exposure to adverse movements in currency exchange rates. Our foreign operations will be exposed to foreign exchange rate fluctuations as the financial results are translated from the local currency into U.S. dollars upon consolidation. Specifically, the U.S. dollar cost of our operations in Canada, manufacturing in Taiwan and conducting clinical trials in India is influenced by any movements in the currency exchange rate. Such movements in the currency exchange rate may have a negative effect on our financial results. If the U.S. dollar weakens against foreign currencies, the translation of these foreign currency denominated transactions will result in increased revenue, operating expenses and net income. Similarly, if the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenue, operating expenses and net income. As exchange rates vary, sales and other operating results, when translated, may differ materially from our or the capital market's expectations.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of our regulatory bodies. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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.

We currently have no products approved for sale, and our lead product candidate is in the pivotal trial stage of clinical development. The success of our business, including our ability to finance the 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. However, given our stage of development, it may be one year or more if we succeed at all, before we have demonstrated the safety and bioequivalence of a product candidate sufficient to warrant approval for commercialization. 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:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete an investigational new drug application, or IND, enabling studies and successfully submit INDs or comparable applications;

- initiation and timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- whether we are required by FDA, or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- 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;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- the convenience of our treatment or dosing regimen;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- 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;
- 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;
- our ability to expand our products, including ALPHA-1062 into multiple indications;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the actual market-size, ability to identify patients and the demographics of patients eligible for our product candidates, which may be different than expected;
- a continued acceptable safety profile following any marketing approval;
- our ability to compete with other therapies;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

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. Accordingly,

we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

We may not successfully expand our pipeline of product candidates. If we are not successful in identifying, developing, in-licensing, acquiring or/and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued development and potential approval of our current product candidates, a key element of our strategy is to identify, develop and commercialize a portfolio of products that help the cognitive and functional symptoms of mild-to-moderate Alzheimer's Disease. A component of our strategy is to evaluate our product candidates in multiple indications, such as mild-to-moderate Alzheimer's Disease, moderate-to-severe Alzheimer's Disease, and TBI. However, we have not yet evaluated ALPHA-1062 or ALPHA-0602 in all of these patient populations and we may find that while we have seen promising results in one neurodegenerative disease, that effect is not replicated across other indications with promising similarities. Even if we successfully identify additional product candidates, we may still fail to yield additional product candidates for development and commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our additional product candidates obsolete;
- additional product candidates we develop may be covered by third parties' patents or other exclusive rights;
- an additional product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- an additional product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an additional product candidate may not be accepted as safe and effective by physicians and patients.

We therefore cannot provide any assurance that we will be able to successfully identify, in-license or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunities may be limited.

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

The Company expects to out-license the limited use of ALPHA-1062 solely for applications in treating mTBI and TBI to Alpha Seven. The establishment and funding of Alpha Seven as described in this AIF are at the preliminary stage only. There is no guarantee that the Company will be successful at launching Alpha Seven as described in this AIF or at all. If successfully launched, there is no guarantee that Alpha Seven 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 Alpha Seven. In addition, the Company's competitors may challenge the validity or enforceability of its patents or other intellectual property rights, which could result in costly legal proceedings that may adversely affect the Company's financial condition or its ability to out-license its technology to Alpha Seven. Even if the Company is able to out-license its technology or intellectual property to Alpha Seven, it may not receive the expected financial benefits or other advantages from such arrangements, and may face competition from other technologies or companies. The failure to successfully out-license the

technology or intellectual property to Alpha Seven could have a material adverse effect on the Company's financial condition, results of operations, and prospects.

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 markers 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, resulting in increased expected development costs or the delay or prevention of commercialization of ALPHA-1062 for the treatment of mild-to-moderate Alzheimer's Disease.

Even if we obtain regulatory approval for ALPHA-1062, our only product in clinical development will remain subject to regulatory oversight

Even if we obtain any regulatory approval for ALPHA-1062, our lead product, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for ALPHA-1062 may also be subject to a post-approval safety monitoring program, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of ALPHA-1062 or any future lead compound, a regulatory authority may take enforcement actions, such as issuing warnings, fines, or even revoking approval, which could result in delays, financial penalties, reputational damage, and potential legal liabilities for our company:

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize ALPHA-1062 and adversely affect our business, financial condition, results of operations and prospects.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of ALPHA-1062. 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 are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations and prospects.

We may encounter substantial delays in our preclinical studies, clinical trials and obtaining NDA approval or may not be able to conduct or complete our preclinical studies or clinical trials or receive NDA approval 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. Further, even once completed, the process to receive an NDA can be delayed or unsuccessful.

The timing and success of obtaining NDA approval can be affected by many factors including:

- we may experience general administrative delays in the FDA review and approval process;
- our clinical trial results may be interpreted differently by the FDA and may not be accepted by the FDA upon review;
- the population studied in the clinical trial may not be accepted by the FDA as sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be required to conduct costly and time consuming additional preclinical studies or clinical trials;
- we may be subject to unexpected limitations on how we may promote any approved products;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on end-to-end supply chain management and use;
- we may experience delays or be unable to demonstrate to the satisfaction of the FDA that the applicable product candidate is safe, pure and potent, or effective as for its intended uses; and
- we may experience delays or be unable to demonstrate to the satisfaction of the FDA that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable.

The timing and success of clinical trials can be affected by many factors including:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining, or failure to obtain, regulatory authorization to commence a trial;
- imposition of a temporary or permanent clinical hold by the FDA or comparable foreign regulatory authorities;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- identifying, recruiting and training suitable clinical investigators;
- obtaining institutional review board, or IRB, approval at each trial site;
- new safety findings that present unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical trial operations or study sites;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or

- obtaining sufficient supply of product candidates for use in preclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials or require that we submit additional data or information before allowing a clinical trial to be initiated or continue;
- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates or such requirements may not be as we anticipate; and
- any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. 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. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. 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.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials or other drug development activities that could harm our competitive position. 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 delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a therapeutic candidate, limit the commercial profile of an approved label or result in other 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. Results of our planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. 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. Treatment-related side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

If any of our product candidates receives marketing approval, and we or others later identify undesirable and unforeseen side effects caused by such product, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;

- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

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.

Interim "top-line" and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the "top-line" results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business, financial condition, results of operations and prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

We have conducted, and in the future plan to conduct, clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted clinical trials of our product candidates outside the United States, and plan to continue to do so in the future. The Phase 1 single and multiple ascending dose studies of ALPHA-1062 in healthy volunteers were conducted at the Centre for Human Disease Research (CHDR) in the Netherlands. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, any comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless:

- the data are applicable to the U.S. population and U.S. medical practice;
- the trials were performed pursuant to good clinical practice, or GCP, requirements; and
- if necessary, the FDA is able to validate the data through an on-site inspection.

Many foreign regulatory authorities have similar requirements. In addition, foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable 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 product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may have been more profitable or for which there could have been a greater likelihood of success.

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific diseases. As such, currently we are primarily focused on the development of ALPHA-1062. As a result, we may forego or delay pursuit of opportunities with other product candidates. For example, we have out-licensed ALPHA-1062IN for applications in treating mild traumatic brain injury to a private entity formed by us for the purpose of raising private capital and developing the asset. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific diseases may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

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. We currently carry product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. 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. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

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. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may have access to our confidential information. Our internal information technology systems and infrastructure, and those of any future collaborators and our contractors, consultants, vendors and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization or persons with access to systems inside our organization.

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 prevalent use of mobile devices that access confidential information also increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. We may face increased risks of a security breach or disruption due to our reliance on internet

technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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 while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems 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. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. Moreover, if a computer security breach affects our systems or results in the unauthorized access to or unauthorized use, disclosure, release or other processing of personally identifiable information or clinical trial data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws, and our reputation could be materially damaged. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Risks related to Our Industry

Research and development of pharmaceuticals is a lengthy and inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval.

We are an early stage of clinical development of our only pre-clinical stage product candidates, other than ALPHA-1062. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our product candidates, and we may experience delays or fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trial observations or results that require us to modify the design of our clinical trials;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the cost of clinical trials of our product candidates being greater than anticipated;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it does not meet applicable regulatory criteria;
- any changes to our manufacturing process that may be necessary or desired;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our current and future product candidates. Each of our product candidates will require significant clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical studies that we may conduct may not be acceptable to the FDA or other regulatory authorities or demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

In addition, to obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. We may also rely on collaborators or partners to conduct the required activities to support an application for regulatory approval and to seek approval for one or more of our product candidates. We cannot be sure that any such collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we or any future collaborators or partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions and civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

We are subject to or affected by federal, state and foreign data protection laws and regulations which address privacy and data security. In the United States, numerous federal and state laws and regulations, including the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, which govern the collection, use, disclosure and protection of health-related and other personal information, may apply to our operations and the operations of any future collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and other privacy and data security laws. Depending on the facts and circumstances, we could be subject to significant administrative, civil and criminal penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Further, various states have implemented similar privacy laws and regulations. For example, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA went into effect on January 1, 2020 and grants the California Attorney General the power to bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and as a result may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Foreign data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information data subjects in the EU or the United Kingdom, or UK. The GDPR went into effect on May 25, 2018. Companies that must comply with the GDPR face increased compliance obligations and risk, including robust regulatory enforcement of data protection requirements as well as potential fines for noncompliance of up to €20 million or 4% of annual global revenue of the noncompliance company, whichever is greater. The GDPR imposes numerous requirements for the collection, use, storage and disclosure of personal information of EU or UK data subjects, including requirements relating to providing notice to and obtaining consent from data subjects, personal data breach notification, cross-border transfers of personal information, and honoring and providing for the rights of EU or UK individuals in relation to their personal information, including the right to access, correct and delete their data.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

Moreover, clinical trial subjects about whom we or any of our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could materially and adversely affect our business, financial condition, results of operations and prospects.

Even if the product candidates that we develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for our product candidates and adversely affect our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or any future collaborators' ability to develop, manufacture, promote and sell product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the European Union, or EU, and many other jurisdictions, we and any future collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or any future collaborators fail to comply with the regulatory requirements in international markets or to obtain all required marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and adversely affect our business.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. Moreover, the neurodegenerative field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. 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. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

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, mild Traumatic Brain Injury, and Amyotrophic Lateral Sclerosis. Current generic competitors in the Alzheimer's Disease market include donepezil, rivastigmine, galantamine, and memantine. Branded competitors include Namzaric® by maker Abbvie and newly approved Adlarity® by maker Corium. Alzheimer's Disease companies developing therapeutics for similar indications include large companies with significant financial resources, such as Biogen, Eli Lilly, Corium, Taurz, Vasopharm. Neuren Pharmaceuticals, Abliva, and AB Science. In the Traumatic Brain Injury market, there are no current acute or chronic treatments approved to date. Companies currently in clinical trials for Traumatic Brain Injury include Vasopharm, SanBio/Sumitomo, Ostuka/Avanir Pharmaceuticals, Biogen, and Cellvation.

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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. 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 commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of mild-to-moderate Alzheimer's Diseases, which could give such products significant regulatory and market timing advantages over any of our product candidates. 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.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. See "*Risks Related to Our Intellectual Property*." 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 products and decrease our ability to generate revenue.

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 clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- 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;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, if approved for commercial sale;
- 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;
- limitations or warnings contained in the FDA-approved labeling for our products;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

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. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs. 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. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our lead product candidate involves several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product manufacturing. We have a direct relationship with a manufacturer in Taiwan for our lead candidate, ALPHA-1062. As a result, the supply chain for the manufacturing of our product candidates is complicated, and we expect the logistical challenges associated with our supply chain to grow more complex as our product candidates are further developed.

We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. We generally do not begin preclinical or clinical trials unless we believe we have access to a sufficient supply of a product candidate to complete such study. In addition, any significant delay in, or quality control problems with respect to, the supply of a product candidate, or the raw material components thereof, for an ongoing study could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates.

We have not yet engaged all manufacturers for the commercial supply of our product candidates. Although we intend to enter into such agreements prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our product candidates, we will have no other means of producing our product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of

supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

In addition, to manufacture our product candidates in the quantities which we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and we may need to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels or in adequate quantities, if at all, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved.

We are subject to certain supply chain risks inherent in manufacturing our lead product, ALPHA-1062, and future products with respect to Taiwan. Risks including periodic foreign economic downturns and political instability, which may adversely affect the Company's ability to obtain materials and conduct business in Taiwan.

Our sole manufacturing location for ALPHA-1062 is located in Taiwan. There are risks inherent in manufacturing internationally, including the following: different regulatory environments; difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; fluctuations in foreign currency exchange rates; tax rates in certain foreign countries that may exceed those in the United States and foreign earnings that may be subject to withholding requirements; the imposition of tariffs, exchange controls, or other trade restrictions; general economic and political conditions in countries where we operate or where our customers reside; government control of capital transactions, including the borrowing of funds for operations or the expatriation of cash; potential adverse tax consequences; security concerns and potential business interruption risks associated with political or social unrest in foreign countries where our facilities or assets are located; difficulties associated with managing a large organization spread throughout various countries; difficulties in enforcing intellectual property rights and weaker intellectual property rights protection in some countries; required compliance with a variety of foreign laws and regulations; and differing customer preferences. The factors described above may have a material adverse effect on our business, financial condition, and results of operations.

Foreign economic downturns may affect our results of manufacturing in the future. Additionally, other facts may have a material adverse effect on the Company's business, financial condition and results of operations, including:

- international economic and political changes;
- the imposition of governmental controls or changes in government regulations, including tax laws, regulations, and treaties;
- changes in, or impositions of, legislative or regulatory requirements regarding the pharmaceutical industry;
- compliance with U.S. and international laws involving international operations, including the Foreign Corrupt Practices Act and export control laws;
- restrictions on transfers of funds and assets between jurisdictions; and
- China-Taiwan geo-political instability.

Our Taiwanese partners are critical to our supply chain. Accordingly, our business, financial condition and results of operations may be affected by changes in governmental policies, taxation, inflation or interest rates in Taiwan and by social instability and diplomatic and social developments in or affecting Taiwan which are outside of our control. Since 1949, Taiwan and the Chinese mainland have been separately governed. The PRC claims that it is the only legitimate government in China, including Taiwan and mainland China, and that Taiwan is part of China. Although significant economic and cultural relations have been established between Taiwan and mainland China in the past few years, such as the adoption of the Economic Cooperation Framework Agreement and memorandum regarding cross-strait financial supervision, we cannot assure you that relations between Taiwan and mainland China will not become strained again. For example, the PRC government has refused to renounce the use of military force to gain control over Taiwan and, in March 2005, passed an Anti-Secession Law that authorized non-peaceful means and other necessary measures should Taiwan move to gain independence from the PRC. Past developments in relations between Taiwan and mainland China have on occasion depressed the market prices of the securities of companies doing business in Taiwan. Such initiatives and actions are commonly viewed as having a detrimental effect to reunification efforts between Taiwan and mainland China. Relations between Taiwan and mainland China and other factors affecting military, political or economic conditions in Taiwan could materially and adversely affect our financial condition and results of operations, as well as the market price and the liquidity of our ordinary shares.

As the Company continues to manufacture in Taiwan, our success will depend in part, on our ability to anticipate and effectively manage these risks. The impact of any one or more of these factors could materially adversely affect our business, financial condition and results of operations.

If a situation arises that prohibits us from manufacturing in Taiwan now or in the future, we do believe we would be able to find replacement third-party manufacturer in another country, The Company has begun sourcing from manufacturers at different geographical regions to mitigate the situation, however this could deviate from our current timelines and cost structure. We may be forced to either temporarily or permanently discontinue the manufacturing and sale of our products which could expose us to legal liability, loss of reputation, and risk of loss or reduced profit.

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 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. 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.

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. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the cost of the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amounts we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. 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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, and governmental healthcare plans, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other foreign jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amounts that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our 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. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of biopharmaceutical products, and 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. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. 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.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our current and future drug development programs and product candidates. 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.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our product candidates are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. The patent applications that we own may fail to result in issued patents with claims that cover any of our product candidates in the United States or in other foreign countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable, and vice versa that may affect the regulatory approval process.

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. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if patents do successfully issue based on our patent applications, and even if such patents cover our product candidates, uses of our product candidates, or other aspects related to our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our products and technologies. Other companies may also design around technologies we have patented or developed. Any successful opposition to these patents or any other patents owned by us in the future could deprive us of rights necessary for the successful commercialization of any of our product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other

technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act was signed into law on September 16, 2011 and includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We note that certain of our U.S. patents directed toward ALPHA-1062 and ALPHA-0602 are set to expire in 2026. In relation to these particular expiring patents we have other patents which we believe are sufficient to cover our patent protection needs in relation to ALPHA-1062 and ALPHA-0602. However, we may be wrong in this assessment or face unforeseen difficulties in relation to our patent coverage with could adverse impact the Company.

Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world, which may harm our business.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services, and our competitive position in the international market would be harmed.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

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. 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. If market exclusivity is granted for an NCE, during the exclusivity period, the FDA may not accept for review or approve an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug 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. 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, for example new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Clinical investigation exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of an NDA for the same drug. However, an applicant submitting an NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates including our lead product candidate ALPHA-1062 can be challenged by third parties.

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an application under Section 505(b)(2) or an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be

required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our drug candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering any of our product candidates, our competitors might be able to enter the market earlier than anticipated, which would harm our business.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

The issuance of a patent does not give us the right to practice the patented invention. A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. Third parties may also have blocking patents that could prevent us from marketing our products or practicing our own patented technology. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may in-license, and any failure by us or our potential licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we may license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our potential licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our product candidates including our lead product candidate, ALPHA-1062.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. However, while certain research, development and commercialization activities may be protected by the safe harbor provision of the Hatch-Waxman Amendments, other activities may subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise harm our business, results of operation, financial condition or cash flows. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could adversely impact the price of our Common Shares. If securities analysts or investors perceive these results to be negative, it could adversely impact the price of our Common Shares. The occurrence of any of these events may harm our business, results of operation, financial condition or cash flows.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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 in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Therefore, 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.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may become involved in lawsuits to protect or enforce our patents or our other intellectual property rights, which could be expensive, time consuming and unsuccessful. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Competitors may infringe or otherwise violate our patents or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the

USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates.

We may not be able to detect or prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could harm the price of our Common Shares.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or seek some other non-litigious action or solution.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Common Shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our Common Shares may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensor. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities and have a harmful effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could adversely impact the price of our Common Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product including our lead product candidate, ALPHA-1062.

The United States has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclose, resulting in harm to our business and competitive position.

Because we expect to rely on third parties to manufacture our product candidates, and we expect to continue to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims that our employees, consultants, independent contractors or we have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the confidential information of their former employer, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may harm our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would harm our business, results of operations and financial condition.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. Such a loss of patent protection could harm our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make product that is similar to product candidates we intend to commercialize that is not covered by the patents that we own;
- we, or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own;
- we or any collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may harm our business.

Should any of these events occur, they could significantly harm our business and results of operations.

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. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. 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. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. We cannot provide any assurance that any product candidates we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have conducted, managed or completed only a limited number of large-scale or pivotal clinical trials, and have managed the regulatory approval process with the FDA or any other regulatory authority, only a limited number of times. Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to

market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

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.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We will have to comply with requirements concerning advertising and promotion for any future products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. We may not promote products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from any future products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our product candidates. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

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.

We operate in a highly regulated industry. 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. New laws, regulations or judicial decisions or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could adversely affect our business, operations and financial condition. 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.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017 repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. The Trump administration issued executive orders which sought to reduce burdens associated with the Affordable Care Act and modified how it was implemented. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court which heard oral arguments in the case on November 10, 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.

Further changes to and under the Affordable Care Act remain possible, although the new Biden administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug and biologic prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Budget Control Act of 2011 has resulted in reductions in spending on certain government programs, including aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year. These reductions have been extended until 2030 unless additional Congressional action is taken.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

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.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, without limitation:

- the U.S. federal civil and criminal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the HITECH and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2023, the U.S. federal physician transparency reporting requirements will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy, security and disposal of personal information and health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof; and
- similar data protection and healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal data, including the GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union and European Economic Area (including with regard to health data).

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in

recent years as a result. In addition, government funding of the U.S. Securities and Exchange Commission (SEC) and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents,

contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences

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 the date of this AIF, we have 4 full-time and 1 part-time contractors in total. 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. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including personnel focused on research and development and, if our product candidates receive marketing approval, sales;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize ALPHA-1062 and our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

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

Our officers also serving as officers of Alpha Seven may give rise to a conflict of interest which may adversely impact the Company's interests.

Our Chief Executive Officer, Michael McFadden, and our Chief Operating Officer, Lauren D'Angelo, both serve as officers of Alpha Seven, a corporation in which we own approximately 47.5% of the issued and outstanding shares of common stock. This could give rise to a conflict of interest in which our interests are different than those of Alpha Seven or in which the interests of our officers in relation to Alpha Seven are different than the interests of the Company and its shareholders. In such cases, if we are unable to effectively manage the conflict of interest through the oversight of our Board, our interests in Alpha Seven may be adversely impacted.

Our success is dependent on our ability to attract and retain highly qualified management and other clinical and scientific personnel.

Our success depends in part on our continued ability to attract, recruit, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon 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 clinical trials and preclinical studies, regulatory approvals or the

commercialization of ALPHA-1062 or any future product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, employment candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our Common Shares.

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 expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of

our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services, which is our preferred marketing and sales strategy, on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

We may explore strategic collaborations that may never materialize or may fail.

We may attempt to broaden the global reach of our platform by selectively collaborating with leading therapeutic companies and other organizations. As a result, we may periodically explore a variety of possible additional strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. In the event we do form such collaborations, we intend to retain significant economic and commercial rights to our programs in key geographic areas that are core to our long-term strategy. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We may seek to grow our business through acquisitions of complementary businesses, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could harm our financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product portfolio, manufacturing capabilities, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including: problems assimilating the acquired service offerings, products or technologies; issues maintaining uniform standards, procedures, quality control and policies; unanticipated costs associated with acquisitions; diversion of management's attention from our existing business; risks associated with entering new markets in which we have

limited or no experience; increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and unanticipated or undisclosed liabilities of any target.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired service offerings, products or technologies. Our potential inability to integrate any business, products or technologies effectively may adversely affect our business, results of operations and financial condition.

We will incur increased costs and demands upon management as a result of being a public company in the United States.

The Company may list its Common Shares on a U.S. stock exchange. As a public company listed in the United States, the Company would incur significant additional legal, accounting and other expenses that we did not incur as a private company or a public company in Canada, including the cost of director and officer liability insurance. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the CSE, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board, on committees of our Board, or as members of senior management.

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 the economies in Canada and the United States, 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.

Sales of a substantial number of shares of our common shares in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common shares in the public market after any legal restrictions on resale discussed in this prospectus lapse, the trading price of our common shares could decline.

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 20.3% and 58.2% of our outstanding Common Shares and Preferred Shares, respectively, 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.

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.

Our Common Shares are subject to the penny stock rules, which make it more difficult to trade our Common Shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price per share of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before effecting a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that, before effecting any such transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Shares, and therefore stockholders may have difficulty selling their Common Shares.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative, low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. The FINRA requirements may make it more difficult for broker-dealers to recommend that their customers buy our Common Shares, which may have the effect of reducing the level of trading activity in our Common Shares. As a result, fewer broker-dealers may be willing to make a market in our Common Shares, reducing a stockholder's ability to resell our Common Shares.

General Risk Factors

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

At December 31, 2023, the Company had, for Canadian tax purposes, non-capital losses aggregating approximately $40.2 million. These losses are available to reduce taxable income earned by Alpha Canada in future years and expire between 2035 and 2040. Additionally, as of December 31, 2023, the Company had, for United States of America tax purposes, non-capital losses aggregating approximately $974,000. These losses are available to reduce taxable income earned by the Company U.S. subsidiary in future years and expire in 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.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Globally, interest rates have been increased multiple times in response to concerns about inflation and there may be further increases to interest rates in the future. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and increasing tensions between China and Taiwan have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget. We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our Common Shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain U.S. based research coverage by securities and industry analysts. If no or few securities or industry analysts commence or continue coverage of us, the trading price for our Common Shares would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our Common Share performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

Our business will be subject to the risks of climate change, natural catastrophic events, world events, and man-made problems such as power disruptions or terrorism.

A significant natural disaster, such as an earthquake, a fire, a flood, or significant power outage could have a material adverse impact on our business, results of operations and financial condition. Climate change or a natural disaster could affect our personnel, data centers, supply chain, manufacturing vendors, or logistics providers' ability to provide materials and perform services such as manufacturing products or assisting with shipments on a timely basis. In addition, climate change could result in an increase in the frequency or severity of natural disasters. Climate change or a natural disaster may also affect our ability to occur raw materials needed for manufacturing and production. Likewise, we could be subject to other man-made problems, including but not limited to power disruptions and terrorist acts. Although we will maintain incident management and disaster response plans, in the event of a major disruption caused by a natural disaster or man-made problem, we may be unable to continue its operations and may endure system interruptions, reputational harm, delays in our development activities, lengthy interruptions in service, breaches of data security and loss of critical data, and our insurance may not cover such events or may be insufficient to compensate it for the potentially significant losses we may incur. Acts of terrorism and other geo-political unrest could also cause disruptions in our business or the business of our supply chain, manufacturers, logistics providers, partners, or customers or the economy as a whole. Recently, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof as well as any counter measures or retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely affect regional economies and the global economy. The situation remains uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, disrupt our manufacturing and supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations. Any disruption in the business of its supply chain, manufacturers, logistics providers, partners or customers that impacts sales at the end of a fiscal quarter could have a significant adverse impact on our financial results. All of the aforementioned risks may be further increased if disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays or cancellations of customer orders, or the delay in the manufacture, deployment, or shipment of our products, our business, financial condition, and results of operations would be adversely affected.