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

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-42403

Alpha Cognition Inc.
(Exact Name of Registrant as Specified in its Charter)

British Columbia	**N/A**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1452 Hughes Street, Ste. 200 Grapevine, Texas	**76051**
(Address of Principal Executive Offices)	(Zip Code)

(858) 344,4375
(Registrant's Telephone Number, including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Title of each class:	**Trading Symbol**	**Name of each exchange on which registered:**
Common Stock, no par value	ACOG	The Nasdaq Stock Market LLC

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-Accelerated Filer ☒
Smaller Reporting Company ☒ Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $149,495,700.

The number of shares of Registrant's Common Stock outstanding as of March 31, 2026 was 21,774,104.

DOCUMENTS INCORPORATED BY REFERENCE

To the extent herein specifically referenced in Part III, portions of the Registrant's Definitive Proxy Statement on Schedule 14A for the 2025 Annual Meeting of Stockholders are incorporated herein. See Part III.

Auditor Firm Id:	199	Auditor Name:	CBIZ CPAs P.C.	Auditor Location:	New York, New York

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance, as well as our plans, objectives and expectations for our business operations and financial performance and condition. All statements other than statements of historical facts included in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that "we believe" or similar statements reflect our beliefs and opinions on the relevant subject.

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;
- the timing and possible outcome of regulatory and legislative matters, including, without limitation, planned FDA, EU and other regulatory approval processes;
- future plans, objectives or economic performance, or the assumption underlying any of the foregoing; and
- other expectations of the Company.
- 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 ZUNVEYL formerly known as 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 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 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;
- risks related to acquisitions and related integrations; and
- risks related to our common stock.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section entitled "Risk Factors" and elsewhere in this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, including applicable Canadian laws, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report , completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report by these cautionary statements.

PART I

ITEM 1. BUSINESS

Business Overview

We are a biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's disease ("AD"), for which there are limited or no treatment options. We focus on the development of commercial manufacturing and commercial sales of ZUNVEYL oral tablet formulation. Our commercial development program for ZUNVEYL is primarily focused on building a long-term care ("LTC") commercial team that can focus on providing key points of differentiation, exploiting key issues with existing Acetylcholinesterase inhibitors ("AChEI") treatments, and franchising potential additional indications and new products.

We launched ZUNVEYL on March 19, 2025 and will target the largest volume nursing homes specializing in Alzheimer's Disease, leveraging an account-based sales team with demonstrated success in LTC, positioning ZUNVEYL with Medicare payors, and developing strategic and clinical partnerships with consultant pharmacists and long-term care pharmacies. We have three additional pre-clinical development programs: ZUNVEYL in combination with memantine for the treatment of moderate-to-severe Alzheimer's disease, ALPHA-1062 sublingual formulation, ALPHA-1062 sublingual formulation for the treatment of cognitive impairment with mild traumatic brain injury (mTBI; otherwise known as concussion), and ALPHA-0602, ALPHA-0702 & ALPHA-0802, the latter two programs 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).

ZUNVEYL, 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. ZUNVEYL'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. ZUNVEYL is in pre-clinical development in combination with memantine to treat moderate to severe Alzheimer's disease, in pre-clinical development with sublingual formulation for patients suffering from dysphagia, and to study a sublingual formulation for cognitive impairment with mTBI.

Our other pre-clinical assets previously included ALPHA-0602 and ALPHA-0702 & ALPHA-0802 (Progranulin and Progranulin GEM's), which are expressed in several cell types in the central nervous system and in peripheral tissues, promotes cell survival, regulates certain inflammatory processes, and play a significant role in regulating lysosomal function and microglial responses to disease. As the assets were pre-clinical and did not add material value to the Company, the Company did not develop these assets further and instead terminated its licensing agreement related to the assets but retained certain royalties and payments from the licensor in relation to any future developments of the assets.

The Company exercised a reversion of rights for ALPHA-1062 for TBI, pancreatitis, and related conditions in January 2025 and has brought ALPHA-1062 for mTBI and related conditions, ALPHA-1062 for Acute pancreatitis back to the Company to develop both compounds for said conditions.

Our Strategy

The Company's principal business objectives are to:

1) Obtain commercial success with the newly FDA-approved ZUNVEYL delayed release oral tablet formulation indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults (Alzheimer's disease). On July 26, 2024, the Company received this FDA approval. The Company will now focus on the development of commercial manufacturing and commercial sales of ZUNVEYL oral tablet formulation. Even though ZUNVEYL was approved, it may not achieve commercial success. The Company hired its commercial team, and salesforce in the first quarter 2025. The official commercial launch was announced on March 19, 2025 and ZUNVEYL is now available by prescription in pharmacies nationwide. The Company believes that it has sufficient capital to achieve operating profitability by 2027, provided the Company executes its commercial plan in LTC market and does not advance compounds in the pipeline.

2) Pursue its pre-clinical assets when the timing and costs to the Company permit.

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

- Execute commercialization of the FDA-approved ZUNVEYL oral formulation. ZUNVEYL is the second oral therapy available for Alzheimer's patients in the past decade. The Company may pursue new business opportunities for commercial and/or development partners both domestically and internationally.

- **Commercialization** – The Company completed commercialization preparations for ZUNVEYL in the first quarter of 2025 and initiated commercial launch on March 19, 2025. Since launch, the Company has been executing its commercialization strategy, including targeting the LTC market, prioritizing LTC customers, communicating the product's clinical positioning, and implementing marketing and operational plans designed to support adoption.

  Commercial supply of ZUNVEYL was established in the first quarter of 2025, and wholesalers were stocked with the necessary dosage strengths of ZUNVEYL (5 mg, 10 mg, and 15 mg) to support launch and ongoing distribution.

- Development of Pre-clinical Assets- The Company plans to Pursue non-dilutive funding sources for ALPHA-1062 for Cognitive Impairment with mTBI. The Company is advancing benzgalantamine sublingual formulation as a treatment for mild-to-moderate Alzheimer's disease in 2025. The company has initiated formulation modification for this product and plans to run a comparative pharmacokinetic study vs. ALPHA-162IN and ZUNVEYL. Pending the outcome of this study, the company would meet with FDA to align on the clinical study program required for approval of the sublingual formulation.

Commercialization

ZUNVEYL Alzheimer's Disease Commercialization

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 ZUNVEYL in the U.S. The Company has completed sufficient planning and launched ZUNVEYL on March 19, 2025 using a specialty sales force that focuses on LTC physicians in the U.S. LTC physicians who treat elderly patients that reside in nursing homes also make pharmacologic decisions in concert with the LTC treatment team. Third party prescribing data 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 ZUNVEYL to take market share in the overall AChEI market. The sales force executes potential key points of label differentiation and exploit key issues with existing AChEI medications. The Company is actively engaged in securing formulary coverage for ZUNVEYL with U.S. payors and negotiating agreements with pharmacy benefit managers. The extent and timing of coverage will depend on individual payor determinations, including considerations related to pricing, rebates, and clinical differentiation.

Additionally, the Company intends to seek strategic partnerships to expand promotional efforts and physician promotional coverage. Since ZUNVEYL received FDA regulatory approval, the Company expects to seek distribution partners for major territories, identified as Europe, LATAM (Mexico, Central and South America), Middle East, 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 resources. Please see the section entitled "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.

On January 8, 2025, the Company announced an exclusive licensing agreement with CMS International Development and Management Limited ("CMSI") for the development, manufacturing and commercialization of ZUNVEYL (benzgalantamine) in Asia (excluding Japan), Australia and New Zealand. ZUNVEYL is a next generation acetylcholinesterase inhibitor approved in the US for the treatment of mild-to-moderate Alzheimer's disease. Terms of the agreement total $44 million, which includes $3 million in total upfront payments split into tranches and development and commercial milestone payments. Additionally, ACI is eligible to receive royalties on net sales of ZUNVEYL in Asia (excluding Japan), Australia and New Zealand. CMSI will be responsible for the regulatory, development, manufacturing, and commercialization of ZUNVEYL in the licensed territories.

On January 14, 2025, the Company announced the strategic appointments of Jen Pesa, Vice President of Commercial; Jack Kelly, Head of Market Access; Rommel Fernandez, Vice President of Corporate Strategy and Operations; and Kurt Grady, Vice President of Medical Affairs. These hires mark significant milestones in building Alpha Cognition's commercial and medical teams.

On March 19, 2025, the Company announced the official commercial launch of ZUNVEYL.

Potential ZUNVEYL coverage and reimbursement in the United States

The Company believes payer access will be an important factor in the continued adoption of ZUNVEYL. While prescription demand is increasing, payer coverage and reimbursement remain in the early stages of expansion. As formulary coverage broadens and prior authorization processes are implemented or streamlined, the Company believes patient access may improve and support additional prescription growth.

The Company's commercial team is actively engaged in securing formulary coverage with payors and negotiating contracts with pharmacy benefit managers ("PBMs"). As of the date of this report, the Company has executed agreements with two of the four major national PBMs and is focused on downstream implementation across affiliated health plans.

The Company expects that implementation of these PBM agreements and expansion of plan-level coverage will occur over time, which may improve patient access to ZUNVEYL. However, the timing, scope, and terms of coverage are subject to individual payor decisions and ongoing negotiations.

The Wholesale Acquisition Cost (WAC) for ZUNVEYL has been set at $820 per month. This pricing reflects the company's commitment to ensuring affordability and access while supporting the commercialization strategy in the $2 billion U.S. Alzheimer's LTC market. This pricing reflects our commitment to balancing patient access with the value of innovative healthcare solutions. By establishing a competitive WAC price, we aim to enhance affordability and ensure patients can benefit from our advanced treatment options. Patients' out-of-pocket cost for treatment with ZUNVEYL will depend on their length of treatment and their insurance. The WAC price serves as the benchmark for negotiations with payers and channel partners, influencing reimbursement dynamics and market access strategy. Alpha Cognition remains focused on optimizing patient access and formulary positioning to drive adoption and long-term revenue growth.

Competitive Conditions and ZUNVEYL Positioning

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

There are five symptomatic drug treatments that have been approved by the FDA to date for mild to moderate dementia of the Alzheimer's type in adults, including ZUNVEYL.

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

4) Donepezil transdermal system (marketed under the brand name Adlarity by Corium)

   a. Approved in 2022, branded transdermal patch

   b. Acetylcholinesterase inhibitor drug class, once-weekly transdermal system

   c. Indicated for mild-to-moderate and moderate-to-severe stages of Alzheimer's disease

5) Benzgalantamine (marketed under the brand name ZUNVEYL by Alpha Cognition)

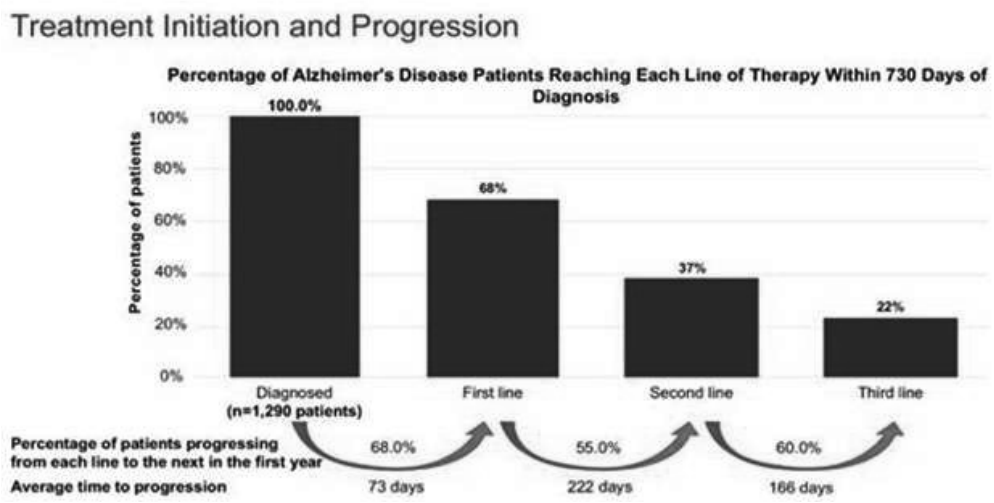
   a. Approved in 2024, commercially available in Q1 2025

   b. Acetylcholinesterase inhibitor drug class, oral BID medication

   c. Indicated for mild-to-moderate stage of Alzheimer's disease

The FDA approved Aducanumab (marketed under the branded name Adulhelm by Biogen) in 2021 and lecanemab (marketed under the branded name Leqembi by Eisai) for mild-to-moderate Alzheimer's disease. Adulhelm was the first disease modifying treatment (DMT), but due to several issues associated with the drug, including Centers of Medicare and Medicaid Services ("CMS") restricting overage, it was not easily accessible and was only covered for qualified clinical trial patients. Biogen has announced that it is discontinuing sale of Adulhelm by the end of 2024. 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 five 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 express dissatisfaction with the currently approved symptomatic treatments options.

Our solution: ZUNVEYL

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

- Established efficacy of galantamine with cognitive, behavioral symptom 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 passes through the GI tract as an inactive compound to potentially minimize GI side effects (nausea, vomiting, and diarrhea)
- No incidence of insomnia in the FDA approved label for ZUNVEYL

According to primary market research conducted by and for the Company, including a report prepared by a third-party paid for by the Company in October 2021, we believe the market research confirms that based on the product attributes listed above, 88% of LTC prescribers are likely to prescribe ZUNVEYL, with a 29% preference share.

ZUNVEYL, also known as ALPHA-1062 Delayed Release Oral Tablet Formulation, Manufacturing

With respect to the manufacturing of ZUNVEYL, the Company has entered into agreements with specialized contract manufacturing organizations located in Taiwan for the manufacturing of the ZUNVEYL 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.

ZUNVEYL 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.

ZUNVEYL 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 for ZUNVEYL 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 and select Asian countries. 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.

Alzheimer's Disease Mild-to-Moderate Stage Program

Disease and Market Overview

An estimated 6.7 million Americans age 65 and older were living with Alzheimer's dementia in 2023[(1)]. This 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[(1)]. 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.

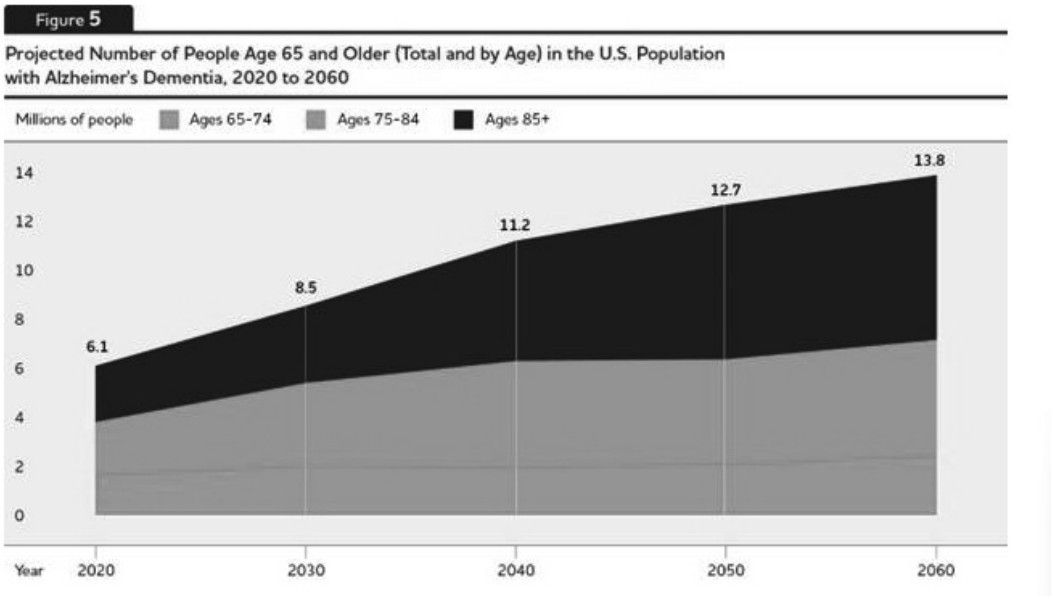
Of the patients with Alzheimer's disease, the vast majority, approximately 2.5 million[(1)], have been diagnosed with mild Alzheimer's disease. Mild Alzheimer's disease is expected to grow over the next decade, signaling a continued need for symptomatic drugs with greater efficacy and fewer side effects.

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).

(1) Alzheimer's Association. 2023 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2023;19(4). DOI 10.1002/alz.13016.

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 US. Approximately 70% of patients with mild Alzheimer's disease, 80% with moderate, and 75% with severe Alzheimer's disease are on drug-treatment. On average, it can take up to 2.5 months from diagnosis to treatment, but can take up to 2 years, and roughly 32% will never go on treatment. Patients are treated primarily with symptomatic medications to help the cognitive and functional symptoms of Alzheimer's disease. In addition to symptomatic treatments, patients are often prescribed behavioral and psychiatric medications for depression, hallucinations, aggression and agitation.

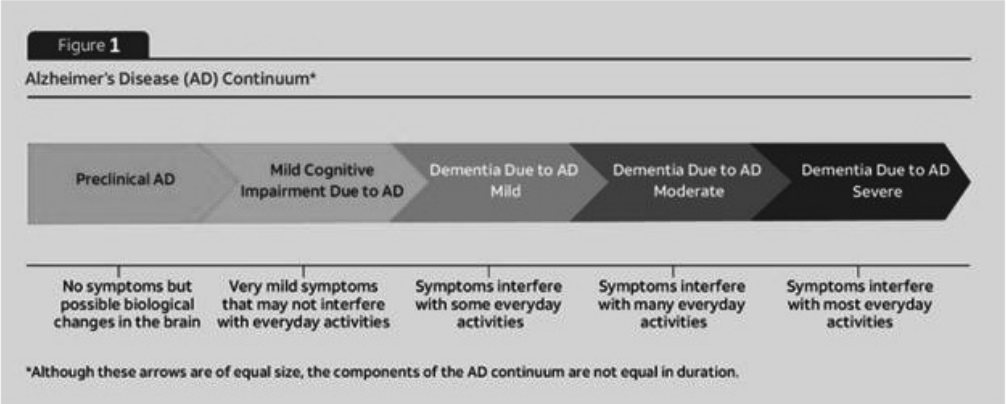
The current and forecasted prevalence of Alzheimer's disease is a large societal and public health care crisis. More than 1 in 9 elderly people have Alzheimer's disease (age 65 or older), and of that group, 73% are actually 75+ years old with a majority (61%) being women. Alzheimer's disease was officially 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.



Adapted from Alzheimer's Facts and Figures, 2023, page 30.

Symptoms

There 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 to go 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 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 poll. In addition to providing help with daily activities, caregivers are also providing emotional, physical, communication, and financial support. As the disease progresses and the patient exhibits 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, Page 50

Long-term care homes and death rates

LTC 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 disease 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 disease 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.

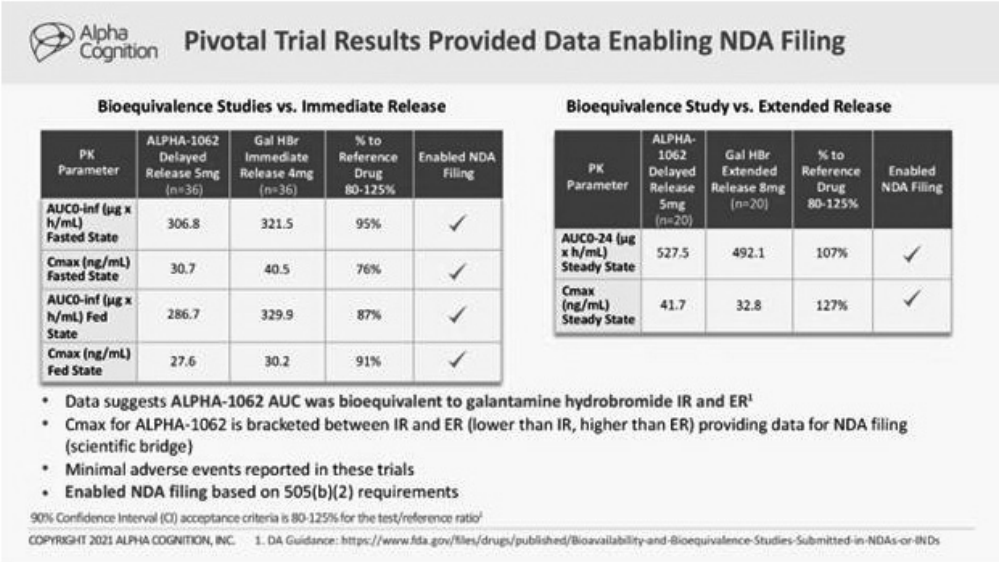
Alzheimer's disease was officially listed as the sixth-leading cause of death in the United States in 2019. In 2020 and 2021, when COVID-19 became the third-leading cause of death, Alzheimer's disease was the seventh-leading cause of death; official counts for 2022 are still being compiled. Alarmingly, 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 disease or another dementia died.

ALPHA-1062 (now known as ZUNVEYL) Clinical Development

The original nasal formulation of ALPHA-1062 was used to conduct Phase I human studies, initially by Neurodyn Life Sciences Inc. ("NLS") a former related party through common shareholders, and subsequently, on completion of the ALPHA-1062 license agreement, by the Company. The Phase I human studies included a SAD Study followed by a MAD 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).

Bioavailability and Bioequivalence Pivotal Trials: The Company completed two studies (fed and fasted) in Q2 2022 (from April to June) and a third in Q3 2022 (from July to August). All studies were completed in India with Vimta Labs, Inc., a clinical research organization with significant experience in running bioanalytical and bioequivalence studies. The studies were designed to demonstrate pharmacokinetic equivalence in healthy subjects compared to the reference listed drug galantamine hydrobromide immediate release (fed and fasted) and galantamine hydrobromide extended release, which are standard of care treatments for patients with mild to moderate Alzheimer's disease. The studies were designed in accordance with FDA 505(b)(2) guidance for industry. 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 from the bioequivalence studies suggested 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 (<2%) reported for ALPHA-1062 delayed release oral tablet formulation during these studies. With these bioavailability and bioequivalence pivotal study results, the Company filed an NDA for ALPHA-1062 delayed release oral tablet formulation for the treatment of mild to moderate dementia of the Alzheimer's type in adults during Q3 2023, with FDA approval for the U.S. market on July 26, 2024.

The following table summarizes the results of each of the two ZUNVEYL, formerly known as ALPHA-1062 delayed release oral tablet formulation, Pivotal Studies (fed and fasted) — Bioequivalence/Bioavailability ("BABE") Study vs. Immediate Release ("IR") (completed in June 2022) and an additional BABE Study vs. Extended Release ("ER") (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 ALPHA-1062 (or benzgalantamine) 5mg delayed release oral tablet formulation 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) are 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 delayed release oral tablet formulation. 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 delayed release oral tablet formulation to galantamine hydrobromide appeared to be 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 delayed release oral tablet formulation 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 delayed release oral tablet formulation 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 delayed release oral tablet formulation appeared to be demonstrated based on overall drug exposure in both the fed and fasted states, and the Cmax with ALPHA-1062's delayed release oral tablet 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 delayed release oral tablet formulation appeared to be 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 should allow for a scientific bridge to both formulations of the reference standard galantamine hydrobromide.

Single-dose administration of ALPHA-1062 delayed release oral tablet formulation was well tolerated with no adverse events reported.

BABE Study vs. Extended Release

During August 2022, the Company announced results from an additional bioequivalence study with ALPHA-1062. The Company elected to conduct this additional study which was designed to demonstrate PK equivalence between ALPHA-1062 5mg delayed release oral tablets and 8 mg galantamine hydrobromide extended release capsules, when dosed to steady state. Bioequivalence appeared to be 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 bioavailability and bioequivalence pivotal data released in June, establishes bioequivalence to both formulations of galantamine hydrobromide, based on the approval of the FDA on July 26, 2024.

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 delayed release oral tablet formulation twice daily, or galantamine hydrobromide 8mg ER capsules once daily, for 7 days. After a one-week washout period, subjects were then crossed over to the other treatment arm and dosed for 7 days. 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 suggested that in healthy adult volunteers treated to steady state, ALPHA-1062 delayed release oral tablet formulation was bioequivalent to galantamine hydrobromide extended release. In the pre-specified primary analysis, ALPHA-1062 delayed release oral tablet formulation 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 delayed release oral tablet formulation 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 delayed release oral tablet formulation and supplements 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 delayed release oral tablet formulation 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 delayed release oral tablet formulation was provided by FDA to support commercial strengths in commercially marketed product. The Company believes it has demonstrated the required stability endpoints for twelve months of long-term stability data in the three potential strengths of ALPHA-1062 delayed release oral tablet formulation. The RESOLVE trial was a trial designed to measure adverse events in an Alzheimer's population and provide label enabling data for ALPHA-1062 delayed release oral tablet formulation. 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 that the ALPHA-1062 RESOLVE trial was not required for the submission of an NDA, the Company filed its NDA for ALPHA-1062 delayed release oral tablet formulation in mild-to-moderate Alzheimer's disease in Q3 2023, allowing the Company to include additional CMC stability data in the NDA filing. See the section entitled "Risk Factors — 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".

Alzheimer's Disease Moderate-To-Severe Stage Program

Disease and Market Overview

Our second program is a combination oral product of benzgalantamine and memantine 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 memantine-containing product. In the moderate stage of Alzheimer's disease symptoms become more intense, significantly affecting patients' 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 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 LTC 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 LTC 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, 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.

Following the launch of ALPHA-1062 now known as ZUNVEYL for the treatment of mild-to-moderate dementia of the Alzheimer's type in adults (Alzheimer's disease), we plan 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 a 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 being established for the mild-to-moderate indication targeting LTC 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

US 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. Since ZUNVEYL received approval for mild-to-moderate Alzheimer's disease, the payer team intends to glean additional insights from their customers to determine commercial price and potential payer coverage by the payer community.

Pre-Clinical Product Candidates

Alzheimer's Disease Mild-to-Moderate Stage: ALPHA-1062 sublingual formulation

ALPHA-1062 sublingual formulation will also be developed as an alternative formulation for patients who suffer from dysphagia (inability to swallow). A number of Alzheimer's patients are estimated to suffer from dysphagia and utilize alternative liquid or patch formulations for medicine administration. A systematic review (***Dement Neuropsychol***. 2022 Jul-Sep; 16(3): 261-269) estimated dysphagia prevalence of greater than 80% of moderate to severe patients with Alzheimer's. The sublingual formulation would allow for a dissolvable tablet that could provide medicine to these patients in an alternative method of administration. The Company completed an internal, unpublished in vitro study to evaluate absorption of 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 has been initiated to further modify the sublingual formulation and run comparative pharmacokinetic studies vs. ALPHA0162IN and benzgalantamine oral. The data will be discussed with FDA to determine next steps for this program.

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

On July 26, 2024, the Company received approval for ALPHA-1062 indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults (Alzheimer's disease), and the Company plans to progress the development of a combination product candidate comprising ALPHA-1062 + memantine. The product candidate combination is currently in pre-clinical development 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 product candidate. The Company believes an ALPHA-1062 + memantine product candidate may utilize a triple mechanism of action approach to optimize therapeutic effect. We believe that 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 formulation is in early development stages and further development will be contingent upon the Company obtaining additional capital resources through financing and further alignment with the FDA on the scope and requirements of a development program.

ALPHA-1062

mTBI: The Company has completed a pre-clinical study of ALPHA-1062 in mTBI. The Company is encouraged by the preclinical data and met with the FDA in Q2 2023 to discuss program advancement 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 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 to initiate the additional pre-clinical toxicity and manufacturing work in the future. The Company would then be in the position to advanceALPHA-1062.

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

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

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

The Company completed SAD with intranasal administration. The study was a double-blind, comparator and placebo-controlled, sequential cohort, SAD in 58 healthy human subjects with ALPHA-1062IN in doses of 5.5, 11, 22, 33, 44mg compared to 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 a MAD with intranasal administration. The study was a randomized, double-blind, placebo-controlled study with multiple intranasal doses of ALPHA-1062IN in 48 healthy human 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.

Traumatic Brain Injury (TBI) Market

According to secondary market research conducted by and for the Company, including a report prepared by a third-party paid for by the Company dated June 2020, we believe that TBI is a highly prevalent, and increasingly common condition, with nearly 3 million diagnosed events occurring in the United States alone in 2019 with an estimated 91% of such events being mTBI. 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[1], representing an estimated, based on events data above, 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 to pursue a study of ALPHA-1062 Intranasal ("ALPHA-1062IN") 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 mTBI 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.

Intellectual Property

The Company has developed, filed, and exclusively licensed (from NLS) a significant intellectual property portfolio with respect to ZUNVEYL also known as ALPHA-1062 and ALPHA-1062IN, or benzgalantamine, 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. 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.

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
United States	US 9,763,953	Granted	12/1/2026
	US 10,265,325	Granted	09/22/2026
China	CN 102007129	Granted	04/14/2028

In China, 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.

A patent term extension (PTE) of U.S. 9,763,953 has been filed to potentially extend the term of this granted patent. 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. We cannot guarantee whether the USPTO will grant any term extension, including the requested extension of time.

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/ Application number	Status	Expiry Date
United States	US11,077,119	Granted	08/07/2033

In the U.S., the patent has been granted for sublingual administration of ALPHA-1062.

Blood Brain Barrier IV (BBB IV): Self-preserving compositions and multi-use dispensers for administering ALPHA-1062 (PCT application WO2022236396).

Jurisdiction	Application number	Status	Estimated Expiry Date (20-year term)
United States	18/560,636	Pending	05/14/2041
China	2021800981674	Pending	05/14/2041
Hong Kong	62024094093.7	Pending	05/14/2041
Europe	21941020.6	Pending	05/14/2041

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/Application number	Status	Estimated Expiry Date (20-year term)
United States	11,795,176 12,157,743 18/965,776 19/247,344	Granted Granted Pending Pending	01/13/2042
Europe	22738869.1	Pending	01/13/2042
Singapore	11202304626U	Pending	01/13/2042
Russia	2023121087	Pending	01/13/2042
Mexico	MX/a/2023/008276	Pending	01/13/2042
Korea	10-2023-7024970	Pending	01/13/2042
Japan	2023-565641	Pending	01/13/2042
Israel	303907	Pending	01/13/2042
China	2022800098271	Pending	01/13/2042
Hong Kong	62024086161.2	Pending	01/13/2042
	62024091747.1	Pending	01/13/2042
Canada	3,205,859	Pending	01/13/2042
Brazil	BR 11 2023 013926 0	Pending	01/13/2042
Australia	2022208641	Pending	01/13/2042

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 Canadian Intellectual Property Office (CIPO) has acknowledged novelty and inventive step of the claims of the PCT application. The USPTO granted two patents issued as US 11,795,176 and 12,157,743. Two further US continuation applications have been filed to pursue other ALPHA-1062 gluconate solid forms as disclosed in the original application.

Blood Brain Barrier VI (BBB VI): ALPHA-1062 for Treating Traumatic Brain Injury (TBI) (PCT application WO2023092231).

Jurisdiction	Application number	Status	Estimated Expiry Date (20-year term)
United States	18/549,309	Pending (allowed)	est. 11/25/2042
United States	19/566,889	Pending	est. 11/25/2042
Japan	2024-531248	Pending	11/25/2042
Europe	22896916.8	Pending	11/25/2042
China	2022800777268	Pending	11/25/2042
Canada	3,238,221	Pending	11/25/2042
Australia	2022399054	Pending	11/25/2042
Hong Kong	62025105479.2	Pending	11/25/2042
	62025101639.5	Pending	11/25/2042

This invention is based on preclinical animal studies in TBI showing enhanced therapeutic benefit, suited for multi-use intranasal administration, building on the antimicrobial properties of ALPHA 1062. National phases from the PCT application have been initiated as above and remain pending. The US application was allowed and is intended for grant March 2026, and subsequent to the 2025 year end, a further US continuation has been filed.

Blood Brain Barrier VII (BBB VII): ALPHA-1062 for Treating Post Concussive Syndrome (PCS) (PCT application PCT/CA2024/050691)

Jurisdiction	Application number	Status	Estimated Expiry Date (20-year term)
Europe	EP24809904.6	Pending	5/24/2044
China	2024800336565	Pending	5/24/2044
United States	19/486,720	Pending	est. 5/24/2044

This invention is based on treating cognitive impairment in patients with persistent post-concussion symptoms (PCS) after TBI, using ALPHA 1062. A US provisional application was filed May 25, 2023 (U.S. prov. appln. no. 63/504,292). An international PCT application was filed in May 2024. National phases in Europe, the United States and China have been filed.

Blood Brain Barrier VIII (BBB VIII): Coated tablets for pH-dependent release of benzgalantamine PCT application PCT/CA2025/050154).

Jurisdiction	Patent/Application number	Status	Estimated Expiry Date (20 year term)
United States	12,208,167	Granted	est. 02/06/2044
	19/036739	Pending	02/06/2044
China	2025101260517	Pending	02/06/2045
Taiwan	114104405	Pending	02/06/2045
Hong Kong	42025111587.9	Pending	02/06/2045

This invention is based on an oral tablet formulation for administering ALPHA 1062, employing a coating for pH dependent release. The formulation enables beneficial pharmacokinetic properties and side effect profile. A US application was filed on February 6, 2024 and is now issued as a patent. A US continuation was filed. An international PCT application was filed, as were patent applications in China, Taiwan and Hong Kong. Additional national phases are intended.

Blood Brain Barrier IX (BBB IX): Process for Preparing Benzgalantamine and Salts Thereof

Jurisdiction	Patent/Application number	Status	Estimated Expiry Date (20 year term)
United States	19/090,242	Pending	est. 03/25/2045
China	202510391815.5	Pending	03/31/2045

This invention is based on an improved method of benzgalantamine synthesis. A US priority application and application in China have been filed. A PCT and Taiwan application are intended.

Blood Brain Barrier X (BBB X): Methods of Achieving Specific Pharmacokinetic Effects for Galantamine

Jurisdiction	Patent/Application number	Status	Estimated Expiry Date (20 year term)
United States	19/278,583	Pending	est. 07/23/2045

This invention is based on methods of achieving specific pharmacokinetic effects for galantamine as described in the ZUNVEYL label. A US priority application has been filed.

Blood Brain Barrier XI (BBB XI): Dosage Regimens for Benzgalantamine

Jurisdiction	Patent/Application number	Status	Estimated Expiry Date (20 year term)
United States	12,551,491	Granted	est. 07/23/2045

This invention is based on specific dosage regimes for administering benzgalantamine as described in the ZUNVEYL label. Subsequent to the 2025 year end, a US priority application has been filed and has been issued by USPTO.

Blood Brain Barrier XII (BBB XII): Amorphous solid form of Benzgalantamine gluconate

Jurisdiction	Patent/Application number	Status	Estimated Expiry Date (20 year term)
United States	19/427,793	Pending	est. 12/19/2045

This invention is based on amorphous forms of benzgalantamine and amorphous solid dispersions. A US priority application has been filed.

Employees

The Company has 71 full-time employees. Employees work virtually in offices located in Vancouver, BC and Dallas/Fort Worth, Texas.

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.

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 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 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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant ODD, to a drug or therapeutic biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a biological product available in the United States for this type of disease or condition will be recovered from sales of the product. ODD must be requested before submitting a BLA. After the FDA grants ODD, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has ODD receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as not being able to supply the product for patients or showing clinical superiority to the product with orphan exclusivity.

Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

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.

505(b)(2) NDAs

The FDA is authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product for all, or some, of the conditions of use for which the branded reference drug has been approved, or for a new condition of use sought by the 505(b)(2) applicant.

Abbreviated New Drug Applications, or ANDAs

The Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of abbreviated new drug applications ("ANDA") for generic versions of listed drugs. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include clinical data to demonstrate safety and effectiveness. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the reference listed drug. For some drugs, other means of demonstrating bioequivalence may be required by the FDA, especially where the rate or extent of absorption is difficult or impossible to measure. The FDA will approve an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the reference listed drug. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the reference listed drug if it is intended for a different use or if it is not subject to, and requires an approved suitability petition.

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 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 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 disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers with 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 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. 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 that commenced 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.

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 ZUNVEYL, following the marketing approval received on July 26, 2024.

Business Cycle and Seasonality

The Company's business is not expected to be cyclical or seasonal.

Economic Dependence

The Company's business is not expected to be substantially dependent on any single commercial contract or group of contracts either from suppliers or contractors.

Changes to Contracts

The Company does not expect that its business will be materially affected in the current financial year by the renegotiation or termination of any contracts or sub-contracts.

Corporate Structure

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. The Company completed its Qualifying Transaction with Alpha Cognition Canada Inc. (formerly Alpha Cognition Inc.) ("Alpha Canada" or "ACI 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 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 Annual Report.

Competition

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

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

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

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

Implications of Being an Emerging Growth Company

As a company with less than $1.235 billion in revenues during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in 2012. As an emerging growth company, we expect to take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemption from certain executive compensation disclosure provisions requiring a pay-for-performance graph and CEO pay ratio disclosure; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We elected to take advantage of all of these reduced reporting requirements and exemptions, including the longer phase-in periods for the adoption of new or revised financial accounting standards under §107 of the JOBS Act. Our election to use the phase-in periods may make it difficult to compare our financial statements to those of non-emerging growth companies and other emerging growth companies that have opted out of the phase-in periods under §107 of the JOBS Act.

We may use these provisions until the last day of our fiscal year following June 7, 2029. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (i) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (ii) scaled executive compensation disclosures; and (iii) the requirement to provide only two years of audited financial statements, instead of three years.

Implications of Being a Smaller Reporting Company

Rule 12b-2 of the Exchange Act defines a "smaller reporting company" as an issuer that is not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent that is not a smaller reporting company and that:

- had a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter, computed by multiplying the aggregate worldwide number of shares of its voting and non-voting common equity held by non-affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principal market for the common equity; or

- in the case of an initial registration statement under the Securities Act, or the Exchange Act of 1934, as amended, which we refer to as the Exchange Act, for stock of its common equity, had a public float of less than $250 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such stock held by non-affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated initial public offering price of the sstock; or

- in the case of an issuer whose public float as calculated under the previous two bullet points was zero or less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year for which audited financial statements are available.

We believe that we are a smaller reporting company, and as such that we will not be required and may not include a Compensation Discussion and Analysis section in our proxy statements; we will provide only two years of financial statements; and we need not provide the table of selected financial data. We also will have other "scaled" disclosure requirements that are less comprehensive than issuers that are not smaller reporting companies. These "scaled" disclosure requirements may make our securities less attractive to potential investors, which could make it more difficult for our security holders to sell their securities.

Available Information

Electronic copies of the materials we file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and proxy statements, are available to the public at the web site maintained by the SEC at http://www.sec.gov.

We also maintain a website at *www.alphacognition.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this Annual Report on Form 10-K. We have included our website address as an inactive textual reference only.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully all of the risks described below, together with the other information contained in this report, before making a decision to invest in our securities. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline, and you could lose all or part of your investment.

Summary of Risk Factors

Risks Related to Commercialization and Manufacturing

- ZUNVEYL oral tablet formulation 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.

- The market opportunities for ZUNVEYL oral tablet formulation may be smaller than we anticipate.

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

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

- Our product candidates have not previously been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process that is more efficient and cost-effective to commercialize our potential products, which may not be successful.

- The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those drugs and decrease our ability to generate revenue.

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

Risks Related to Our Financial Position

- We are a commercial stage biopharmaceutical company in the early stages of commercial development of our one product 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.

- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve commercial success with ZUNVEYL formerly known as ALPHA-1062 oral tablet formulation, our one FDA approved product and continued development and commercialization of our other product candidates, if approved.

- We have not completed an Alzheimer's disease patient tolerability study for ZUNVEYL 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 will need substantial additional capital to meet our financial obligations and to pursue our business objectives, including the commercialization of ZUNVEYL oral tablet formulation. 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.

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

Risks Related to Our Business Development

- Our business is heavily dependent on commercial success of of ZUNVEYL oral tablet formulation, our only FDA approved product, and the development and commercialization of any future product candidates that we may develop or acquire.

- 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.

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

- 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.

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

- We have conducted all of our clinical trials to date outside of the United States, 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.

- 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 identified material weaknesses in our internal control over financial reporting which are in the process of being remediated, and if we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

Risks Related to Our Industry

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

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

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

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

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

Risks Related to 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, 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.

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

- 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, ALPHA-1062.

- 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.

- 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 disclosed, resulting in harm to our business and our competitor position.

- 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.

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

- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

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

Risks Related to Government Regulation

- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, expensive, time consuming and inherently unpredictable.

- ZUNVEYL oral tablet formulation and any of our other products that receive regulatory approval will remain subject to regulatory scrutiny.

- Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

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

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.

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

- 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.

- 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.

Risks Related to Our Common Stock

- Our stock price may be volatile, and you may not be able to resell common stock at or above the price you paid.
- An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the initial public offering price.
- We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.
- Risks related to the Company being a "passive foreign investment company" under United States tax laws.
- If we sell common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.
- Concentration of ownership of our voting securities, including common stock and Class B Preferred Series A Stock, among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.
- Sales of a substantial number of our common stock in the public market could cause our stock price to fall.
- We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock;
- 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.

General Risk Factors

- Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.
- We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that could materially and adversely affect our business, financial condition, results of operations and prospects.
- 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

Risks Related to Commercialization and Manufacturing

ZUNVEYL oral tablet formulation 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.

ZUNVEYL may fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. ZUNVEYL and 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 ZUNVEYL or our other 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 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 following the approval of ZUNVEYL or if we receive regulatory approval to market any of our future 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 ZUNVEYL may be smaller than we anticipate.

We have received FDA approval for ZUNVEYL for mild-to-moderate dementia of the Alzheimer's type in adults (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 ZUNVEYL, the potential target populations for mild-to-moderate Alzheimer's disease 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 future regulatory approvals 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 involve 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, ZUNVEYL, and future products with respect to Taiwan. Risks including periodic foreign economic downturns and political instability, which may adversely affect our ability to obtain materials and conduct business in Taiwan.

Our sole manufacturing location for ZUNVEYL 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 stock.

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 not previously been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we are working on developing 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 not previously 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, 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 ZUNVEYL and our other product candidates which may obtain approval 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 a small, newly formed 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 ZUNVEYL or our other product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

We have only recently established a small marketing and sales organization. In order to commercialize ZUNVEYL and our other product candidates, which may obtain approval, 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 other product candidates receive regulatory approval, we expect to expand our 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 Financial Condition

We are a commercial biopharmaceutical company with one product 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 approximately $20.6 million and $14.6 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately $97.1 million. We have only one product, ZUNVEYL formerly known as ALPHA-1062, approved for commercialization.

We have devoted substantially all our financial resources and efforts to the commercialization of ZUNVEYL and development of our other 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 and we continue the commercial roll out of ZUNVEYL and pursue our other product candidates. 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:

- continue establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize ZUNVEYL oral tabulation formulation formerly known as ALPHA-1062 and any other product candidates for which we may obtain regulatory approval;
- conduct our ongoing and planned clinical trials of ALPHA-1062, as well as initiate and complete additional clinical trials;
- continue our clinical validation of ALPHA-1062 for moderate-to-severe Alzheimer's disease and explore the potential of ALPHA-1062IN related to mTBI;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- 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.

Our ability to continue to generate revenue and achieve profitability depends significantly on our ability to achieve commercial success with ZUNVEYL oral tablet formulation, our one FDA approved product, and continued development and commercialization of our other product candidates, if approved.

To date, we have generated approximately $6.8 million in revenue from the commercialization of ZUNVEYL To continue to generate revenue and become and remain profitable, we must succeed in the commercialization of ZUNVEYL and developing and eventually commercializing our other product candidates. This will require us to be successful in a range of challenging activities, including commercial manufacturing, marketing and sales of ZUNVEYL, completing preclinical testing and clinical trials of our other product candidates, obtaining regulatory approval of our other product candidates, and manufacturing, marketing and selling any other product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. Outside of our commercial development activities for ZUNVEYL, we are only in the preliminary stages of most of these activities. 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 and no prior 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 successfully obtained regulatory approval for only one product, ZUNVEYL oral tablets, and began to commercialize ZUNVEYL in 2025. Prior to beginning commercialization efforts in 2025, we have no history of commercializing products. 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 capital to meet our financial obligations and to pursue our business objectives, including the continued commercialization of ZUNVEYL oral tablet formulation. 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. Developing commercial manufacturing, marketing and sales is expensive and uncertain which could take a long time to complete. We may not achieve commercial success with ZUNVEYL. Similarly, 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 continue our commercialization activities for ZUNVEYL and our ongoing clinical trials of our other product candidates, initiate future clinical trials of our other product candidates, prepare for commercialization activities of our other product candidates and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue is primarily derived from sales of ZUNVEYL as a result of our commercial development activities. If we obtain marketing approval for 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, 2025, we had approximately $66.1 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, will be sufficient for us to fund our ongoing operating expenses, commercialization expenses, and capital expenditures requirements through at least the next 12 months. We may need to raise additional capital to fund our operations and commercial plans after 12 months. ZUNVEYL is expected to require substantial capital to continue our commercialization efforts and bring the product to market in the US. 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 and commercialization of ZUNVEYL, including manufacturing, distribution, marketing and sales, obtaining favorable insurance coverage and reimbursement decisions from governmental and third-party payors, 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 other 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 ZUNVEYL 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.

We expect to incur significant commercialization expenses related to product manufacturing, sales, marketing, distribution, and continued R&D of ZUNVEYL.

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 that are contracted in foreign currencies will be exposed to foreign exchange rate fluctuations as the financial results are translated from the local currency into U.S. dollars. Specifically, the U.S. dollar cost of our operations in Canada, API manufacturing in Taiwan and manufacturing of ZUNVEYL 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. Currently, our revenue generating agreements are settled in U.S. dollars, however, we may in the future enter into revenue contracts in foreign currencies if and when we expand commercialization of ZUNVEYL. The extent contracts related to our operating costs or revenue are settled in a foreign currency, if the U.S. dollar weakens against foreign currencies, the translation of these foreign currency denominated transactions could result in increased revenue decreased operating expenses and increased net income (decreased net loss). Similarly, if the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions could result in decreased revenue, increased operating expenses and decreased net income (increased net loss). As exchange rates vary, sales and other operating results, when translated, may differ materially from our or the capital market's expectations.

Risks Related to Our Business Development

Our business is heavily dependent on the commercial success of ZUNVEYL oral tablet formulation, our only FDA approved product, and the development and commercialization of any future product candidates that we may develop or acquire.

The NDA for ZUNVEYL oral tablets was approved by the FDA on July 26, 2024, but all our other product candidates are in the pre-clinical stage. The success of our business, including our ability to finance our Company and generate revenue in the future, will primarily depend on the commercial success of ZUNVEYL, our only FDA approved and commercially produced product, and the development, regulatory approval and commercialization of our other product candidates. We cannot be certain that ZUNVEYL will experience commercial success or that our other product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

The commercial success of ZUNVEYL and the clinical and commercial success of any future product candidates that we may develop or acquire will depend on a number of factors, including the following:

- the continued commercial success of ZUNVEYL, either independently or with marketing service providers;
- the effectiveness of our sales and marketing strategy and operations, and obtaining market acceptance of ZUNVEYL, including garnering market share from existing and future treatment alternatives;
- maintaining compliance with all regulatory requirements applicable to ZUNVEYL and our commercial activities, including the post-marketing requirements and post-marketing commitments required by the FDA;
- the continued acceptability of the safety profile of ZUNVEYL and the occurrence of any unexpected side effects, adverse reactions or misuse, including potential business impact such as the need to withdraw the product (either voluntarily or as mandated by the FDA), loss of support by the advocacy communities or loss of positive corporate reputation resulting in related unfavorable media coverage in these areas;

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete an 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 the 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 ZUNVEYL into multiple indications;
- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- our ability to successfully develop a commercial strategy and thereafter commercialize our other 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 future 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.

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. Biogen's Aduhelm, a monoclonal antibody administered via infusion, received accelerated approval from the FDA on June 7, 2021, but Biogen has announced that it will discontinue marketing Aduhelm by the end of 2024. 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 further approvable or marketable products. Since 2003, over 500 clinical studies in Alzheimer's have been completed and only Aduhelm, Adlarity and now our product ZUNVEYL have been approved by the FDA, compared to higher success rates for all other drug candidates.

ZUNVEYL remains subject to regulatory oversight.

Even though we obtained regulatory approval for ZUNVEYL, 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. FDA has required that we conduct further root cause investigation into observe high variability of the dissolution data for ZUNVEYL oral tables and develop new dissolution methods and acceptance criteria and to report to FDA by February 28, 2025. ZUNVEYL also remains 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 of ZUNVEYL or any future product candidate, 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 the commercial success of ZUNVEYL and adversely affect our business, financial condition, results of operations and prospects.

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.

For our other product candidates, 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 trials may fail to show efficacy and/or safety sufficient for approval, or the results of such trials 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;
- approval 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, an institutional review board (IRB) 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 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 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.

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 ("GLP") requirements or good clinical practice ("GCP") requirements, respectively. 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 IRBs 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.

In addition, our patient tolerability study and other clinical trials may only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, our product candidates may cause unforeseen safety events when evaluated in larger patient populations. Further, clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If following marketing approval of ZUNVEYL (which was received on July 26, 2024) or of any of our future product candidates, 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 becomes 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 becomes 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. For example, we initially conducted our bioavailability and bioequivalence pivotal clinical trials of ALPHA-1062 in collaboration with Vimta Labs, Inc in Hyderabad, India. In addition, 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 future 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 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 future 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 commercialization and further development of ZUNVEYL oral tablets. As a result, we may forego or delay the pursuit of opportunities with other product candidates. For example, we plan to out-license 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 state 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 ZUNVEYL 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 exceeds 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. Following the marketing approval of ZUNVEYL (which was received on July 26, 2024) or if and when we obtain approval for marketing any of our future 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. As a result of the COVID-19 pandemic, 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.

We identified material weaknesses in our internal control over financial reporting which are in the process of being remediated, and if we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. The Sarbanes-Oxley Act of 2002 requires, among other things, that we evaluate our systems and processes and test our internal controls over financial reporting to allow management and our independent registered public accounting firm, as applicable, to report on the effectiveness of our internal control over financial reporting.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. For example, in the course of preparing our financial statements for fiscal the fiscal year ended December 31, 2025, we identified a material weakness in our internal control over financial reporting regarding the lack of effective internal control over the recording and processing of warrants and stock option liabilities. To address this material weakness, we made changes to our internal control framework and controls, as set forth in further detail in Item 9A “Controls and Procedures” and remediated this material weakness.

We cannot be certain that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent or avoid potential future material weaknesses, including with regard to the matters previously remediated. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business or otherwise. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. As such, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be adversely affected.

Risk related to Our Industry

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

Our ZUNVEYL oral formulation for mild-to-moderate dementia of the Alzheimer’s type in adults (Alzheimer’s disease) is our only product that has FDA approval. All our other product candidates are in the pre-clinical stage of development. 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 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, mTBI, 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 TBI market, there are no current acute or chronic treatments approved to date. Companies currently in clinical trials for TBI 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 the section entitled "*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 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, ZUNVEYL formerly known as 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 is issued 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 the earliest filed application in a family. 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 ZUNVEYL 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 ZUNVEYL and ALPHA-0602. However, we may be wrong in this assessment or face unforeseen difficulties in relation to our patent coverage with could adversely 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.

We did not receive any FDA exclusivity associated with the approval of our NDA 218549 for ZUNVEYL.

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

If a product candidate 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 be issued 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.

One of our patent listings in the Orange Book has an inadvertent inaccuracy which may subject us to administrative proceedings before the FDA or litigation claims.

Our listing in the Orange Book for USP 9763953 is inadvertently inaccurate in that it currently states that the patent expires on May 16, 2027 when the patent actually expires on December 1, 2026. While we have submitted for a correction on this inaccuracy, which we expect to occur in the next publication of the Orange Book, the inaccuracy could subject us to administrative proceedings before the FDA, litigation claims against us for an inaccurate listing and could potentially give rise to penalties for the Company for perjury.

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, ZUNVEYL.

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 Act, 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 stock and warrants. If securities analysts or investors perceive these results to be negative, it could adversely impact the price of our common stock and warrants. 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 stock and warrants.

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 stock 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 our common stock 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 stock. 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 manufacture ZUNVEYL or commercialize our future 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, ZUNVEYL.

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 disclosed, 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.

We have not yet registered our trademarks in certain jurisdictions. Failure to secure those registrations could adversely affect our business.

None of our trademarks are registered with the U.S. Patent and Trademark Office or any such foreign office. If we are unable to secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business. Any trademark applications we have filed for our product or product candidates or may file in the future are not guaranteed to be allowed for registration, and even if they are, we may fail to maintain or enforce such registered trademarks. During trademark registration proceedings in any jurisdiction, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our business, financial condition, results of operations and growth prospects.

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 only submitted for regulatory approval of our lead product and have not submitted any of our other product candidates. We have not obtained regulatory approval for any product candidate other than ZUNVEYL for mild-to-moderate dementia of the Alzheimer's type in adults (Alzheimer's disease), and it is possible that none of our other 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 and completed only a limited number of pivotal clinical trials, have limited experience in managing the regulatory approval process with the FDA and have not received approval for any of our product candidates from the FDA or any other regulatory authority. 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 following our regulatory approval of ZUNVEYL or for a future product candidate, our products will remain subject to regulatory scrutiny.

ZUNVEYL, as well as any of our future product candidates if approved, 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 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 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, ZUNVEYL 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 extended 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 March 30, 2026, we had 72 full-time employees and 1 part-time contractor 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 ZUNVEYL, 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, 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 ZUNVEYL 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 ZUNVEYL and our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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 ZUNVEYL 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 stock, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

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.

As a public company listed in the United States, we will 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, 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 of directors, on committees of our board of directors or as members of senior management.

Risks Related to Our Common Stock

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

The trading price of our common stock 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 COVID-19 pandemic and world events. These factors include those discussed in this "Risk Factors" section of this Annual Report and others such as:

- results from, and any delays in, our current and future clinical trials with ZUNVEYL or any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- announcements of the regulatory approval of ZUNVEYL or approval or disapproval for any future product candidates;
- failure or discontinuation of any of our research and development programs;
- the termination of any future collaborations or license agreements;
- delays in the commercialization of ZUNVEYL or any future product candidates;
- public misperception regarding the use of our product candidates;
- acquisitions and sales of new products or product candidates, technologies or businesses;
- manufacturing and supply issues related to our product candidates for clinical trials or future product candidates for commercialization;
- quarterly variations in our results of operations or those of our competitors;
- changes in coverage and recommendations by securities analysts;
- announcements by us or our competitors of new products or product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance;

- any major changes in our board of directors or management;
- new legislation or regulation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the biopharmaceutical sectors;
- general economic conditions in the United States and abroad; and
- other events or factors, including those resulting from pandemics, natural disasters, war, including the ongoing conflict in Ukraine, acts of terrorism or responses to these 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 Company. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock.

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the initial public offering price.

There has been limited trading of our common stock on the OTCQB and CSE exchanges. Although our common stock are now listed on the Nasdaq Capital Market an active trading market may not develop or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your common stock 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 stock and may impair our ability to acquire other product candidates, businesses or technologies using our stock as consideration.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following June 7, 2029, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We believe that we may be a "passive foreign investment company", which may have adverse U.S. federal income tax consequences for U.S. investors.

We believe we were a "passive foreign investment company" (a "PFIC") within the meaning of Section 1297 of the U.S. Internal Revenue Code of 1986, as amended (the "Code") for our most recently completed taxable year and based on current business plans and financial expectations, we expect to be a PFIC for our current taxable year and may be a PFIC in subsequent tax years. If we are a PFIC for any year during a U.S. taxpayer's holding period of common stock, then such U.S. taxpayer generally will be required to treat any gain realized upon a disposition of the common stock, as applicable, or any so-called "excess distribution" received on its common stock, as applicable, as ordinary income, and to pay an interest charge on a portion of such gain or distribution. In certain circumstances, the sum of the tax and the interest charge may exceed the total amount of proceeds realized on the disposition, or the amount of excess distribution received, by the U.S. taxpayer. Subject to certain limitations, these tax consequences may be mitigated if a U.S. taxpayer makes a timely and effective QEF Election (as defined below) or a Mark-to-Market Election (as defined below). In addition, U.S. taxpayers should be aware that there can be no assurances that we will satisfy the record keeping requirements that apply to a QEF (as defined below), or that we will supply U.S. taxpayers with information that such U.S. taxpayers are required to report under the QEF rules, in the event that we are a PFIC. Thus, U.S. Holders may not be able to make a QEF Election. A U.S. taxpayer who makes a Mark-to-Market Election with respect to the common stock generally must include as ordinary income each year the excess of the fair market value of the common stock over the taxpayer's basis therein.

Proposed legislation in the U.S. Congress, including changes in U.S. tax law, may adversely impact us and the value of our Common Stock.

Changes to U.S. tax laws (which changes may have retroactive application) could adversely affect us or holders of the common stock. In recent years, many changes to U.S. federal income tax laws have been proposed and made, and additional changes to U.S. federal income tax laws are likely to continue to occur in the future.

The U.S. Congress is currently considering numerous items of legislation which may be enacted prospectively or with retroactive effect, which legislation could adversely impact our financial performance and the value of the common stock. Additionally, states in which we operate or own assets may impose new or increased taxes. If enacted, most of the proposals would be effective for the current or later years. The proposed legislation remains subject to change, and its impact on us and purchasers of the common stock is uncertain.

In addition, the Inflation Reduction Act of 2022 includes provisions that impact the U.S. federal income taxation of corporations. Among other items, this legislation includes provisions that impose a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that are imposed on the Corporation repurchasing such stock. It remains unclear in certain respects how this legislation will be implemented by the U.S. Department of the Treasury and we cannot predict how this legislation or any future changes in tax laws might affect us or purchasers of the common stock.

It may be difficult to enforce judgments or bring actions outside the United States against us and certain of our directors.

We are a Canadian corporation and certain of our officers and directors are neither citizens nor residents of the United States. A substantial part of the assets of several of these persons, are located outside the United States. As a result, it may be difficult or impossible for an investor:

- to enforce in courts outside the United States judgments obtained in United States courts based upon the civil liability provisions of United States federal securities laws against these persons and the Company; or

- to bring in courts outside the United States an original action to enforce liabilities based upon United States federal securities laws against these persons and the Company.

If we sell our common stock in future financings, stockholders 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, our existing cash, cash equivalents and marketable securities, will be insufficient for us to fund our planned operating and capital expenditures beyond the date that is just several months after the date of this Annual Report, we may from time to time issue additional common stock. These issuances may be at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any our common stock 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, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders will experience additional dilution and, as a result, our stock price may decline.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates are expected to beneficially own approximately 37.1% of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder 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 stockholders purchased their stock at prices substantially below the current market price of our common stock and have held their stock 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 stockholders.

Stock eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their common stock by means of ordinary brokerage transactions in the open market pursuant to effective resale registration statements and Rule 144 promulgated under the Securities Act, subject to certain limitations. Pursuant to Rule 144, non-affiliate stockholders may sell freely after six months, subject only to the current public information requirement. Affiliates may sell after six months, subject to the Rule 144 volume, manner of sale (for equity securities), current public information, and notice requirements. Of the approximately 21.8 million common stock outstanding as of March 26, 2026, approximately 18.7 million shares are tradable by non-affiliates without restriction. Given the limited trading of our common stock, resale of even a small number of common stock pursuant to Rule 144 may adversely affect the market price of our common stock.

Additionally, on July 1, 2025, we filed a resale registration statement on Form S-3 registering the resale of 2,375,735 common stock issuable upon exercise of outstanding warrants issued in private placements prior to our initial public offering and on July 21, 2025, we filed a resale registration statement on Form S-3 registering the resale of 1,289,145 common stock issuable upon exercise of outstanding warrants issued in our convertible note financing in September 2024 and to the underwriters in our initial public offering. We have ongoing registration obligations under the registration rights granted in our past unit financings and in our recent note financing to maintain these resale registration statements. If the warrants are exercised and these registration statements remain effective, the named selling stockholders will be able to freely sell the common stock into the market which may adversely affect the market price of our common stock.

We have also filed registration statements on Form S-8 covering the issuance of an aggregate total of 2,815,975 shares upon exercise or vesting of awards issued to participants under our equity incentive plans. Non-affiliates who receive shares registered under the Form S-8 will be able to freely sell the common stock into the market which may adversely affect the market price of our common stock.

Sales of a substantial number of shares of our common stock 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 stock in the public market after any legal restrictions on resale discussed in this Annual Report lapse, the trading price of our common stock could decline. As of March 30, 2026, we have 21,774,104 common stock outstanding and 316,655 common stock issuable upon conversion of our Class B Series A Preferred Shares, 4,443,446 common stock issuable upon exercise of warrants at a weighted average exercise price of $5.84, 2,471,007 common stock issuable upon exercise of options with a weighted average exercise price of $5.67, 509,713 common stock issuable upon conversion of restricted stock units and 229,642 common shares issuable upon exercise of performance options with a weighted average exercise price of $0.22.

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

At December 31, 2025, the Company had, for Canadian tax purposes, non-capital losses aggregating approximately $57 million. These losses are available to reduce taxable income earned by the Company and Alpha Cognition Canada Inc. in future years and expire between 2035 and 2045. Additionally, as of December 31, 2025, the Company had, for United States of America tax purposes, non-capital losses aggregating approximately $11 million. These losses are available to reduce taxable income earned by the Company's US 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 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 Tax Act, and adversely affect our ability to utilize our NOLs in the future. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

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

We do not currently intend to pay any cash dividends on our common stock 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 stock 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 stock. There is no guarantee that our common stock 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. The Company's functional currency is to the U.S. Dollar. As a result, 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.

General Risk Factors

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. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. 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.

Tariffs and other trade policies could have a substantial impact on our business.

Our business is dependent upon the availability of supplies for our products. U.S. relations with the rest of the world remains uncertain with respect to taxes, trade policies and tariffs, especially under an increasingly volatile political landscape within the U.S. and abroad. Changes in U.S. administrative policy may lead to significant increases in tariffs for imported goods among other possible changes. There have been significant tariffs imposed on imported goods within the U.S. and there are currently indications that future tariffs are likely to be imposed. The imposition of such tariffs may strain international trade relations and increase the risk that foreign governments implement retaliatory tariffs on goods imported from the United States. Similarly, interest rates may continue to rise and create further uncertainty and volatility in the market which would negatively impact our business, financial condition and results of operations. In addition, the potential exists that other countries may impose retaliatory tariffs, which could adversely affect our sales to those countries.

These political and economic changes could have a material effect on global economic conditions and the stability of financial markets and could significantly reduce global trade. In addition to potential increases on tariffs, wars or conflicts could affect our ability to obtain raw materials. Ongoing and future conflicts and other geopolitical events may result in sanctions or other export controls imposed by the U.S. or United Nations.

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 stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We are currently covered by three analysts, Titan Partners, H.C. Wainwrights & Co, and Stonegate Capital Partners. If securities or industry analysts do not continue coverage of us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our commercialization of ZUNVEYL or our clinical trials or operating results fail to meet the expectations of analysts, our stock 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 stock 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.

We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that could materially and adversely affect our business, financial condition, results of operations and prospects.

We are subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we identify any material weaknesses, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could materially and adversely affect our business, financial condition, results of operations and prospects, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs and other third parties to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our stock from the Nasdaq or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations and prospects.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. 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.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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. Additionally, geopolitical tensions and ongoing conflicts in the Middle East, particularly between the United States, Israel and Iran, Israel and Hamas and Israel and Hezbollah, may lead to global economic instability and fluctuating energy prices that could materially affect our business. It is not possible to predict the broader consequences of the conflicts in the Middle East, including related geopolitical tensions and the measures and actions taken by other countries in respect thereof, which could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. The situations in Ukraine and the Middle East remain uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflicts and actions taken in response to the conflicts 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, employee personal information, and clinical trial data, or Information Systems and Data.

We leverage a third party service provider under the direction of our Chief Financial Officer, or CFO, to help management identify, assess and manage our cybersecurity threats and risks. With the assistance of our third-party service provider, we identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including, for example, automated tools for ransomware and virus protection, identity verification tools aimed at ensuring authorized environment access, and ongoing vulnerability assessments.

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures and processes designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: data encryption for certain data, network security controls, data segregation for certain data, access controls, physical security controls, monitoring for certain systems, asset management and tracking, and employee training. We also maintain cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are taken into account in our overall risk management processes. For example, we evaluate identified material risks from cybersecurity threats against our overall business objectives and will report material risks, if identified, to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist management to identify, assess, and manage material risks from cybersecurity threats, including for example, a managed security provider and professional services firms, including outside legal counsel.

We use third-party service providers to perform a variety of functions throughout our business, including, for example, application providers, hosting companies, contract research organizations, and contract manufacturing organizations. We have certain vendor management processes to help manage cybersecurity risks associated with our use of certain of these providers, and, depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, those processes may involve different levels of assessment and risk mitigation measures, including, for example, the imposition of contractual obligations related to cybersecurity on the provider.

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of Company management, including our CFO, leveraging the expertise of our third party service provider. Our CFO has two years of oversight responsibilities for cybersecurity elements and has been involved in the oversight of the implementation of the Company's current cybersecurity measures.

Currently, our CFO is responsible for hiring appropriate personnel, managing external third-party providers, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including to our CFO. As part of those processes, members of management, including our CFO, would work to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes are designed to report certain cybersecurity incidents to the audit committee of the board of directors.

The audit committee receives periodic reports from management concerning our cybersecurity risks and the processes we have implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

ITEM 2. PROPERTIES

The Company does not own or rent any real estate with respect to its corporate head office and laboratory facilities.

Our corporate head office is located at Suite 200 – 1452 Hughes Road, Grapevine, TX, 76051.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are involved in various legal proceedings arising from the normal course of business activities. We are not currently a party to any material legal proceedings nor are we aware of any such legal proceedings contemplated by government agencies. However, from time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

On November 12, 2024, our common stock began trading on the Nasdaq under the symbol "ACOG". Our common stock were previously traded on the CSE, but were voluntarily delisted on December 17, 2024. On November 5, 2024, we completed a reverse stock split of our common stock with a stock split ratio of 1-for-25 ("Reverse Stock Split"). On March 30, 2026, the closing price for our common stock in quoted on the Nasdaq was $5.32.

Holders of Our Common Stock

As of March 30, 2026, we had approximately 119 registered holders of our common stock. This number does not include an indeterminate number of stockholders whose stock are held by brokers in street name through depositaries, including CDS & Co and CEDE & Co.

Dividend Policy

We have paid no dividends on the common stock to date and we do not expect to pay dividends on our common stock in the foreseeable future. Investors in Alpha Cognition's securities cannot expect to receive a dividend in the foreseeable future, if at all. Any future declaration and payment of cash dividends or other distributions of capital will be at the discretion of our board of directors and will depend on our financial condition, earnings, cash needs, capital requirements (including requirements of our subsidiaries), contractual, legal, tax and regulatory restrictions, and any other factors that our board of directors deems relevant in making such a determination.

Recent Unregistered Sales of Equity Securities

None

Repurchases of Equity Securities by Our Company and Affiliated Purchasers

None.

Use of Proceeds

On October 1, 2025, the Company completed a public offering of common stock by issuing 4,651,516 common shares at a public offering price of $6.25 per share and pre-funded warrants to purchase up to 948,484 common shares at a public offering price of $6.249 per share for gross proceeds of approximately $35 million, after deducting discounts and commissions and estimated offering expenses payable by us, of approximately $32.8 million.

The public offering was completed pursuant to the Company's registration statement on Form S-3 (333-289792) which was brought effective by the SEC on August 29, 2025. Titan Partners Group LLC, a division of American Capital Partners, LLC ("Titan Partners Group") acted as the managing underwriter for the offering. In connection with the offering, the Company paid Titan Partners Group an underwriting discount of approximately $2 million. We paid an aggregate total of approximately $341,250 in other expenses, including expense reimbursement to Titan Partners Group, legal and accounting fees, transfer agent fees and printing costs.

On November 13, 2024, the Company completed a public offering of common stock by issuing 8,695,653 common shares at a public offering price of $5.75 per share for gross proceeds of approximately $50 million and net proceeds, after deducting discounts and commissions and estimated offering expenses payable by us, of approximately $46.15 million. The initial public offering was completed pursuant to the Company's registration statement on Form S-1 (333-280196) which was brought effective by the SEC on November 8, 2024, registering 8,695,653 common shares and pre-funded warrants to purchase up to 8,695,653 common shares to gross aggregated proceeds of $50 million. No pre-funded warrants were sold in the offering. Titan Partners Group acted as the managing underwriter for the offering. In connection with the offering, the Company paid Titan Partners Group an underwriting discount of approximately $3 million and a non-accountable expense allowance of $500,000. We also paid Spartan Capital Partners, LLC an investment banking fee of $500,000. We paid an aggregate total of approximately $350,000 in other expenses, including expense reimbursement to Titan Partners Group, legal and accounting fees, transfer agent fees and printing costs.

Consistent with the Company's described use of proceeds in its registration statement, to date the Company has spent approximately $15.32 million of its net proceeds to begin our efforts toward our commercialization and launch of ZUNVEYL formerly known as ALPHA-1062 in Alzheimer's disease; approximately $3.98 million for continued commercial CMC activities (chemistry, manufacturing, and controls); approximately $0.91 million on repayment of outstanding loan and approximately $8.49 million for working capital and general corporate purposes. As of December 31, 2025 the Company has approximately $55.16 million of the net proceeds remaining in the bank.

Exchange Controls

There are no governmental laws, decrees or regulations in Canada that restrict the export or import of capital, including foreign exchange controls, or that affect the remittance of dividends, interest, or other payments to non-resident holders of the securities of Alpha Cognition, other than Canadian withholding tax. See "Certain Canadian Federal Income Tax Considerations for U.S. Residents" below.

Certain Canadian Federal Income Tax Considerations for U.S. Residents

The following summarizes certain Canadian federal income tax consequences generally applicable under the *Income Tax Act* (Canada) and the regulations enacted thereunder (collectively, the "Canadian Tax Act") and the *Canada-United States Income Tax Convention (1980)* (the "Convention") to the holding and disposition of common stock.

Comment is restricted to holders of common stock each of whom, at all material times for the purposes of the Canadian Tax Act and the Convention:

(i) is resident solely in the United States;

(ii) is entitled to the benefits of the Convention;

(iii) holds all common stock as capital property;

(iv) holds no common stock that are "taxable Canadian property" (as defined in the Canadian Tax Act) of the holder;

(v) deals at arm's length with and is not affiliated with Alpha Cognition;

(vi) does not and is not deemed to use or hold any common stock in a business carried on in Canada; and

(vii) is not an insurer that carries on business in Canada and elsewhere;

(each such holder, a "U.S. Resident Holder").

Certain U.S.-resident entities that are fiscally transparent for United States federal income tax purposes (including limited liability companies) are generally not themselves entitled to the benefits of the Convention. However, members of, or holders of, an interest in such entities that hold common stock may be entitled to the benefits of the Convention for income derived through such entities. Such members or holders should consult their own tax advisors in this regard.

Generally, a holder's common stock will be considered to be capital property of the holder provided that the holder is not a trader or dealer in securities, did not acquire, hold or dispose of the common stock in one or more transactions considered to be an adventure or concern in the nature of trade and does not hold the common stock as inventory in the course of carrying on a business.

Generally, a holder's common stock will not be "taxable Canadian property" of the holder at a particular time at which the common stock are listed on a "designated stock exchange" (which currently includes the TSX) unless both of the following conditions are met at any time during the 60-month period ending at the particular time:

(i) the holder, persons with whom the holder does not deal at arm's length, or any partnership in which the holder or persons with whom the holder did not deal at arm's length holds a membership interest directly or indirectly through one or more partnerships, alone or in any combination, owned 25% or more of the issued stock of any class of the capital stock of Alpha Cognition; and

(ii) more than 50% of the fair market value of the common stock was derived directly or indirectly from, or from any combination of, real or immovable property situated in Canada, "Canadian resource properties" (as defined in the Canadian Tax Act), "timber resource properties" (as defined in the Canadian Tax Act), or options in respect of or interests in such properties.

In certain other circumstances, a Common Share may be deemed to be "taxable Canadian property" for purposes of the Canadian Tax Act.

This summary is based on the current provisions of the Canadian Tax Act and the Convention in effect on the date hereof, all specific proposals to amend the Canadian Tax Act and Convention publicly announced by or on behalf of the Minister of Finance (Canada) on or before the date hereof, and the current published administrative and assessing policies of the CRA. It is assumed that all such amendments will be enacted as currently proposed, and that there will be no other material change to any applicable law or administrative or assessing practice, although no assurance can be given in these respects. Except as otherwise expressly provided, this summary does not take into account any provincial, territorial or foreign tax considerations, which may differ materially from those set out herein.

This summary is of a general nature only, is not exhaustive of all possible Canadian federal income tax considerations and is not intended to be and should not be construed as legal or tax advice to any particular U.S. Resident Holder. U.S. Resident Holders are urged to consult their own tax advisers for advice with respect to their particular circumstances. The discussion below is qualified accordingly.

A U.S. Resident Holder who disposes or is deemed to dispose of one or more common stock generally should not thereby incur any liability for Canadian federal income tax in respect of any capital gain arising as a consequence of the disposition.

A U.S. Resident Holder to whom Alpha Cognition pays or is deemed to pay a dividend on the holder's common stock will be subject to Canadian withholding tax, and Alpha Cognition will be required to withhold the tax from the dividend and remit it to the CRA for the holder's account. The rate of withholding tax under the Canadian Tax Act is 25% of the gross amount of the dividend (subject to reduction under the provisions of an applicable tax treaty). Under the Convention, a U.S. Resident Holder who beneficially owns the dividend will generally be subject to Canadian withholding tax at the rate of 15 % (or 5%, if the U.S. Resident Holder who beneficially owns the dividend is a company that is not fiscally transparent and which owns at least 10% of the voting stock of Alpha Cognition) of the gross amount of the dividend.

Certain United States Federal Income Tax Considerations for U.S. Residents

There may be material tax consequences to U.S. Residents in relation to an acquisition or disposition of common stock or other securities of the Company. U.S. Residents should consult their own legal, accounting and tax advisors regarding such tax consequences under United States, state, local or foreign tax law regarding the acquisition or disposition of our common stock or other securities, in particular, the tax consequences of the Company possibly being a PFIC within the meaning of Section 1297 of the United States *Internal Revenue Code.* See the section "Item 1A. – Risk Factors – The Company is possibly a "passive foreign investment company," which would likely have adverse U.S. federal income tax consequences for U.S. shareholders" above.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDIITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements for the fiscal year ended December 31, 2025, and the related notes thereto, which have been prepared in accordance with generally accepted accounting principles in the United States. This discussion and analysis contains forward-looking statements and forward-looking information that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements and information as a result of many factors. See section heading "Special Note Regarding Forward-Looking Statements."

Overview

The Company is a commercial stage biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's disease ("AD"), for which there are limited or no treatment options. The Company focuses on the commercial manufacturing and commercial sales of ZUNVEYL oral tablet formulation. The Company's commercial program for ZUNVEYL is primarily focused on its long-term care commercial team that can focus on providing key points of differentiation, exploiting key issues with existing AChEI treatments, and franchising potential additional indications and new products.

For additional details regarding our business, see the discussion under "*Business*" in Item 1 of Part I of this Annual Report on Form 10-K.

The Company launched ZUNVEYL on March 19, 2025, and targets the largest volume nursing homes specializing in Alzheimer's disease, leveraging an account-based sales team with demonstrated success in LTC, positioning ZUNVEYL with Medicare payors, and developing strategic and clinical partnerships with consultant pharmacists and long-term care pharmacies. Alpha Cognition has set the Wholesale Acquisition Cost (WAC) for its therapeutic product at $820 per month. This pricing reflects the company's commitment to balancing patient access with the value of innovative healthcare solutions. By establishing a competitive WAC price, Alpha Cognition aims to enhance affordability and ensure patients can benefit from our advanced treatment options. Patients' out-of-pocket cost for treatment with ZUNVEYL will depend on their length of treatment and their insurance. The Company has three additional pre-clinical development programs: (1) ZUNVEYL in combination with memantine for the treatment of moderate-to-severe Alzheimer's disease,(2) ALPHA-1062 sublingual oral tablet ("ALPHA-1062IN") formulation for the treatment of cognitive impairment with mild traumatic brain injury (mTBI; otherwise known as concussion) and (3) ALPHA-0602, ALPHA-0702 & ALPHA-0802, also referred to as 'Progranulin' and 'Progranulin GEM's', for the treatment of neurodegenerative diseases including amyotrophic lateral sclerosis, otherwise known as ALS or Lou Gehrig's disease and spinal muscular atrophy (SMA).

ZUNVEYL, is a patented new innovative product being positioned as a next generation acetylcholinesterase inhibitor for the treatment of Alzheimer's disease, with expected minimal gastrointestinal side effects. ZUNVEYL'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. ZUNVEYL is in pre-clinical development in combination with memantine to treat moderate to severe Alzheimer's disease, in pre-clinical development with sublingual formulation for patients suffering from dysphagia, and is in pre-clinical development for cognitive impairment with mTBI.

The Company is the parent company of Alpha Cognition Canada Inc. ("Alpha Canada" or "ACI Canada") which is the parent company of Alpha Cognition USA Inc. ("ACI USA"). As of May 1, 2023, the Company's Common Stock commenced trading on the CSE under the symbol "ACOG", previously the Company's stock were traded on the TSX-V until April 28, 2023, when the Company had them delisted. As of November 12, 2024, the Company's Common Stock commenced trading on The Nasdaq Capital Market under the symbol "ACOG". The Company's stock were voluntarily delisted from the CSE on December 17, 2024.

Operations

As of December 31, 2025, the Company had an accumulated deficit of $97,106,775 which has been primarily financed by equity. The Company had $66,105,189 in cash and cash equivalents, including restricted cash, and $9,130,075 in current liabilities (of which $44,464 is payable from the Company's available restricted cash balance) as of December 31, 2025. The Company's continuing operations, as intended, are highly dependent upon its ability to obtain additional funding and eventually positive generate cash flows. Management is of the opinion that it does have sufficient working capital to fully meet the Company's liabilities and commitments as outlined and planned in the following discussion. Management is of the opinion it will need to raise additional capital to cover upcoming planned Research and Development ("R&D"), continued commercialization of ZUNVEYL and operating costs. Possible sources of such capital may come from our "at the market" facility and future private placements, and public offerings of the Company's Common Stock and funds received from the exercise of warrants and stock options. Additionally, the Company will also consider funding that may arise through partnership activities, including royalties, and debt. There is a risk that additional financing will not be available on a timely basis, on terms acceptable, or at all to the Company.

The Company is also contemplating raising capital by pursuing both dilutive and non-dilutive strategic sources of capital to fully execute its commercialization and operating plans for ZUNVEYL from the FDA. Any additional capital is expected to further support our planned costs for commercial activities.

Components of our Results of Operations

Revenue

The Company generates revenue from product sales and licensing arrangements.

Product Sales, Net

Product revenue consists primarily of sales of the Company's commercial product to wholesalers and pharmacies. Revenue is recognized at a point in time when control of the product transfers to the customer.

Product revenue is recorded net of variable consideration, including expected prompt pay discounts, chargebacks, product returns, recalls, rebates, and consideration payable to customers. Consideration payable to customers includes fees paid to distributors, which are generally calculated as a percentage of product sales and are recognized as a reduction of revenue when the related services are not distinct from the Company's promise to transfer the product. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on gross sales for a reporting period. The amount of variable consideration can vary from period to period due to fluctuations in these deductions.

Licensing Revenue

License revenue consists of revenue from our License, Collaboration and Distribution Agreement with CMS International Development and Management Limited, or CMSI (the "CMSI License Agreement"), including upfront payments, potential milestone and royalty payments, as well as revenue from the sale of active pharmaceutical ingredient ("API"), finished goods, and reimbursable costs.

Our revenue to date has been generated primarily from the upfront payment received from CMSI under the CMSI License Agreement. In addition to the upfront payment, we may also be entitled to development, regulatory, and sales milestone payments, as well as royalties on net sales, upon achieving predefined objectives. We recognize license revenue when the related performance obligations are satisfied. If achievement of a milestone is considered probable and it is probable that a significant revenue reversal will not occur, the associated milestone amount is included in the transaction price.

License revenue also includes revenue from the sale of API and finished goods to CMSI, which are generally priced at cost plus a margin, as well as certain reimbursable pass-through costs. These amounts are recognized on a gross basis and are generally recognized upon shipment or delivery, depending on the applicable shipping terms.

We expect that license revenue under the CMSI License Agreement, and from any potential future licensing arrangements, will fluctuate based on the timing and amount of upfront, milestone, and royalty payments, as well as the level of API sales and reimbursable activities.

Cost of Product Sales

Cost of product sales consists primarily of costs related to the manufacturing of ZUNVEYL, logistics costs, inventory impairment expense, and royalty payments under license or purchase agreements.

Prior to receiving FDA approval in July 2024, costs associated with the manufacturing of ZUNVEYL were expensed as research and development expenses.

Cost of Licensing Revenue

Cost of licensing revenue consists primarily of costs incurred to support the Company's licensing arrangements, including the cost of API and finished goods sold to CMSI, as well as other costs associated with fulfilling obligations under the CMSI License Agreement, including reimbursable pass-through costs.

Research and Development

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred unless there is an alternative future use in other research and development projects or otherwise.

Research and development expenses consists primarily of the following:

- costs related to production of clinical supplies and non-clinical materials, including fees paid to contract manufacturers.
- employee-related expenses, which include salaries, benefits, and stock-based compensation.
- other expenses including travel and consulting services.

Selling, General and Administrative expenses

Selling, general and administrative expenses costs consist of personnel costs, other outside professional services including legal, human resources, audit and accounting services, consulting and pre-commercialization expenses, including selling and marketing costs as well attendance to various conferences. Personnel costs consist of salaries, benefits, and share-based compensation. We expect to continue to incur expenses to support our continued operations as a public company, including expenses related to existing and future compliance with rules and regulations of the stock exchanges on which our securities are now traded, insurance expenses, investor relations, audit fees, professional services and general overhead and administrative costs.

Results of Operations

Comparison of the Year Ended December 31, 2025 and 2024

	For the Year Ended December 31,		Dollar	Percentage
	2025	2024	Change	Change
Revenue				
Product sales, net	$ 6,792,024	$ -	$ 6,792,024	100%
Licensing	3,428,251	-	3,428,251	100
Total revenue	10,220,275	-	10,220,275	100
Operating Expenses				
Cost of product sales, excluding amortization of intangible asset	474,006	-	474,006	100
Cost of licensing revenue	1,441,317	-	1,441,317	100
Amortization of intangible assets	21,546	79,875	(58,329)	(73)
Research and development	1,867,972	3,920,412	(2,052,440)	(52)
Selling, general and administrative expenses	29,076,123	8,012,230	21,063,893	263
Total operating expenses	32,880,964	12,012,517	20,868,447	174
Loss from operations	(22,660,689)	(12,012,517)	(10,648,172)	89
Other income (expense)				
Interest income	1,899,370	161,664	1,737,706	(1,075)
Grant income	81,095	463,881	(382,786)	(83)
Gain (loss) from change in fair value of warrant liabilities	88,155	(3,164,707)	3,252,862	(103)
Other expenses	(77,806)	(237,048)	159,242	(67)
Total other income (expense)	1,990,814	(2,776,210)	4,767,024	(172)
Net loss and comprehensive loss	$ (20,669,875)	$ (14,788,727)	(5,881,148)	40
Net loss per share, basic	$ (1.17)	$ (2.04)	$ 0.87	(43)
Weighted-average outstanding stock, basic	17,680,597	7,247,864	10,432,733	144
Adjusted net loss, diluted	$ (20,846,806)	$ (14,788,727)	$ (6,058,079)	(41)
Weighted-average outstanding stock, diluted	17,681,429	7,247,864	10,433,565	144
Net loss per share, diluted	$ (1.18)	$ (2.04)	$ 0.86	(42)

Revenue

Comparison of Revenue for Year Ended December 31, 2025 and 2024

Revenue increased by $10,220,275, or 100%, from $0 for the year ended December 31, 2024 to $10,220,275 for the year ended December 31, 2025. The increase is due to the start of commercial sales of ZUNVEYL in the first quarter of 2025 and the Company's entrance into the License, Collaboration and Distribution agreement with CMSI (the "CMSI License Agreement") pursuant to which the Company received a non-creditable upfront payment of $3 million in January 2025, of which approximately $179,000 has been deferred. The Company expects that revenue from commercial sales of ZUNVEYL will continue to grow year over year as the Company expands its sale force and implements its sale strategy in the coming fiscal year. The Company is also eligible to receive up to $11 million in development and regulatory milestone payments with CMSI, as well as up to $30 million sales milestone payments.

Cost of Product Sales and Cost of Licensing Revenue

Comparison of Cost of Sales and Cost of Licensing Revenue for the Year Ended December 31, 2025 and 2024

Cost of product sales increased by $474,006, or 100%, from $0 for the year ended December 31, 2024 to $474,006 for the year ended December 31, 2025. The increase is due to the start of commercial sales of ZUNVEYL in the first quarter of 2025. The Company expects that cost of product sales will continue to increase year over year in relation to expected increased sales of ZUNVEYL in the coming fiscal year as the Company expands its sales of ZUNVEYL however the Company does expect to realize some cost savings to scale as ZUNVEYL production and distribution in streamlined and potential cost saving measures in sales strategy is realized in the coming year.

Cost of licensing revenue increased by $1,441,317, or 100%, from $0 for the year ended December 31, 2024 to $1,441,317 for the year ended December 31, 2025. The increase is from salaries; royalty payments, and pass-through-costs, such as consulting fees and active pharmaceutical ingredients, were allocated to activities supporting the CMSI agreement. The Company expects that cost of licensing revenue will continue to decrease year over year until requirements of the CMSI agreement have been fulfilled.

Research and Development expenses

Comparison of Research and Development for the Year Ended December 31, 2025 and 2024

Research and development expenses decreased by $2,052,440, or 52%, from $3,920,412 for the year ended December 31, 2024, to $1,867,972 for the year ended December 31, 2025. The net change is due to decrease is primarily due to lower product development costs of approximately $762,000, and less time allocated to management and employees, which resulted in lower management fees and salaries, share-based compensation and employee costs of approximately $1.2 million.

Selling, General and Administrative Expenses

Comparison of Selling, General and Administrative Expenses for the Year Ended December 31, 2024 and 2023

Selling, general and administrative expenses increased by $21,063,893 or 263%, from $8,012,230 for the year ended December 31, 2024, to $29,076,123, for the year ended December 31, 2025 In support of the Company's expansion in commercial operations and launch of ZUNVEYL, there has been an increase of $13.8 million in management fees and salaries and employee costs, $2.4 million in marketing and commercial operations, increase in regulatory costs of approximately $1.5 million and $1.1 million in other general and administrative expenses. Share-based compensation increased by approximately $4 million primarily due to the grant options issued during the 2025 year end and fair value revaluation of CAD options. Consulting fees have decreased by approximately $1,330,000 due to reduction in services for raising capital.

Interest Income

Interest income consists of interest earned and interest charges on the Company's cash and cash equivalents.

Interest income had a net change of $1,737,706 or 1,075% from interest income, net of $161,664 for the year ended December 31, 2024, to interest income, net of $1,899,370 for the year ended December 31, 2025.

Change in Fair Value of Derivative Liabilities and Conversion of Convertible Debt

The Company used the Monte Carlo Simulation to determine the fair value of the initial recognition of the convertible debentures and conversion feature liability in the 2024 year end. Subsequent to the 2024 year end, the convertible debenture warrants were valued using the binomial lattice model to factor in the redemption features associated with these warrants. This model requires the input of subjective assumptions including expected share price, volatility and interest rate. Changes in the input assumptions can materially affect the fair value estimate and the Company's net loss and liabilities.

The Company uses the Black-Scholes Option Pricing Model to determine the fair value of stock options, and derivative liabilities. This model requires the input of subjective assumptions including expected share price volatility, interest rate, and forfeiture rate. Changes in the input assumptions can materially affect the fair value estimate and the Company's net loss and equity reserves.

The gain of $88,155 for the year ended December 31, 2025, for the fair value of the warrant liabilities was a net change of $3,252,862, or 103%, compared to a loss of $3,164,707 for the year ended December 31, 2024. The net change is mainly attributable to the loss on recognition and revaluation of conversion feature liability of approximately $2 million in the 2024 year end. The net change in the fair value of the warrants was primarily due to the fluctuation in the Company's stock price to the comparative period and the reallocation of the derivative for the 128,578 warrants exercised in the year ended December 31, 2025.

Liquidity and Capital Resources

Sources of Liquidity

The Company does not have sufficient operating revenue to finance its existing obligations and has relied on external financing, such as debt and equity raises, to generate capital to maintain its capacity to meet working capital requirements. The Company has relied on debt and equity raises to finance its operating activities since incorporation. The Company has successfully raised funds that exceed the Company's working capital requirements for the next 12 months from the date of issuance of the consolidated financial statements contained in this report. The Company expects to continue to rely on debt and the issuance of stock, and possibly other non-dilutive financing options to finance its ongoing operations and ongoing plans for commercialization of ZUNVEYL. However, there is a risk that additional financing will not be available on a timely basis or on terms acceptable to the Company.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the commercialization of ZUNVEYL, following the start of sales in the first quarter of 2025, and potentially seek to discover and develop additional product candidates, conduct our ongoing and planned clinical trials and preclinical studies, continue our R&D activities, utilize third parties to manufacture ZUNVEYL, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses. The timing and amount of our funding requirements will depend on many factors, including:

- the costs associated with the production, distribution and sales of ZUNVEYL, including any future expansion of production capabilities, expansion of distribution networks, expansion of our sales force and increased expenses on advertising or related sale costs;
- the costs associated with our licensing arrangements for ZUNVEYL, including increased costs from such arrangements and increasing the number and types of licensing arrangements;
- the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and preclinical studies of ZUNVEYL and any future product candidates we may choose to pursue, including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities and any third-party products used as combination agents in our clinical trials;
- the costs, timing and outcome of regulatory meetings and reviews of ZUNVEYL or any future product candidates, including requirements of regulatory authorities in any additional jurisdictions in which we may seek approval for ZUNVEYL and any future product candidates;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, CMC quality and commercial personnel;
- the costs and timing of establishing or securing sales and marketing capabilities of any future product candidate approval;
- 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 and strategic decision to develop future product candidates other than ZUNVEYL, and the timing of such development, if any;
- 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 terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Based upon our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this filing, will be sufficient to fund our projected base ongoing operating expenses, commercialization costs of ZUNVEYL in AD, ongoing CMC costs, pre-clinical formulation and study R&D work, and ongoing operating costs and capital expenditures through at least the next 12 months. We may choose to raise additional capital to continue to further advance our commercialization plans and ongoing operating costs. However, we may have based our estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expected. The Company may also contemplate raising additional capital by pursuing both dilutive and non-dilutive strategic sources of capital to fully execute its commercial, R&D, and operating plans for ZUNVEYL. Any additional capital would further support our R&D and commercial activities related to U.S. sales of ZUNVEYL in AD.

In August 2025, the Company entered into an ATM agreement with H.C. Wainright & Co., LLC as the sales agent. The Company currently has not utilized the ATM facility.

Until such time, as we can generate substantial product revenue, we expect to finance our operations other capital sources, including current or potential future collaborations, licenses, royalties and other similar arrangements. We do not know what the terms of these future financings will be and whether they will be acceptable to the us or not and, therefore, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent we raise additional capital , your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisitions, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends. If we raise additional funds through collaborations or license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or even cease operations.

Financing Activities

Recent capital raising activities

On September 24, 2024, the Company announced the closing of a $4.545 million bridge financing through the issuance of convertible notes and warrants led by existing investors and select new investors comprised of institutional funds and high-net-worth accredited investors.

- The notes are convertible into common stock of the Company at a conversion price of $10.55 per share. The notes were set to mature on September 24, 2026, had an aggregate face value of $4.545 million and bears interest at a rate of 10% per annum paid in common stock of the Company at the conversion price, subject to certain limitations. The notes were subject to mandatory conversion into common stock of the Company in conjunction with the closing of an offering of securities of the Company for at least $10 million in aggregate gross proceeds in coordination with the simultaneous uplisting of the common stock of the Company onto a United States national securities exchange (a "Qualified Offering"). Such conversion was completed into the securities offered in such Qualified Offering at the lower of (i) the conversion price in effect at such time and (ii) the offering price of the securities in the Qualified Offering. The notes were unsecured and rank senior to the Company's other indebtedness.

- The notes were sold along with warrants to purchase common stock of the Company at an exercise price of $10.55 for a five-year term. Each investor received warrants sufficient to purchase such number of common stock equal to the principal amount of notes such investor purchased divided by the conversion price of the notes. Each investor will receive an additional 50% of warrants with identical terms upon the closing of a Qualified Offering, as described above. The exercise price of the warrants is subject to adjustment upon the completion of a Qualified Offering to the lower of (i) the then existing exercise price, (ii) the exercise price of any common stock purchase warrants issued in the Qualified Offering or (iii) if no common stock purchase warrants are issued in the Qualified Offering, the closing price of the common stock on the Canadian Securities Exchange (as converted into U.S. dollars) immediately prior to the pricing news release of the Qualified Offering.

On November 13, 2024, the Company completed a public offering of common stock by issuing 8,695,653 common stock at a public offering price of $5.75 per share for gross proceeds of approximately $50 million. In connection with the US public offering, the Company's Common Stock began trading on The Nasdaq Capital Market on November 12, 2024.

The completion of the public offering of common stock was a "Qualified Offering" under the Company's convertible notes, which automatically converted into 801,413 common stock at closing of the public offering at a price of $5.75 per share, being the public offering price in the Qualified Offering. The amount converted consisted of the converted principal amount of convertible notes and interest through November 13, 2024.

Additionally, as a result of the closing of the Qualified Offering, the Company issued an additional 215,421 warrants exercisable to acquire 215,421 Common Stock with an exercise price of $7.19 per share and the exercise price of the Company's existing 430,835 warrants issued in connection with the offering of the convertible notes was repriced from $10.55 per share to $7.19 per share.

On December 12, 2024, the underwriter of the Company's underwritten U.S. public offering partially exercised its over-allotment option to purchase an additional 488,506 common stock at the public offering price of $5.75 per share for additional gross proceeds of $2.8 million.

On October 2, 2025, the Company completed a public offering of Common Stock by issuing 4,651,516 of Common Stock at a public offering price of $6.25 per share and 948,484 pre-funded warrants exercisable to Common Stock with an exercise price of $0.001 per share for total gross proceeds of approximately $35 million. In connection with this offering, the Company incurred underwriting fees of approximately $2.11 million.

On October 17, 2025, the underwriter of the Company's public offering exercised its over-allotment option in full to purchase an additional 840,000 of Common Stock at the public offering price of $6.25 per share for additional gross proceeds of approximately $5.25 million and underwriting fees of $341,250

The following table includes our cash flow data for the periods indicated:

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2025, and 2024:

	For the Year Ended December 31,		Dollar	Percentage
	2025	2024	Change	Change
Consolidated Statement of Cash Flows Data				
Cash used in operating activities	$ (20,380,367)	$ (7,755,654)	$ (12,624,713)	163%
Cash used in investing activities	$ (293,489)	$ (26,701)	$ (266,788)	999%
Net cash provided by financing activities	$ 38,214,963	$ 54,851,864	$ (16,636,901)	(30)%

Cash used in operating activities

Cash used in operating activities increased by $12,624,713 to $20,380,367 for the year ended December 31, 2025, from $7,755,654 for the comparative period. The purchase of API and manufacturing activity resulted in higher cash outflows than the previous year of approximately $3.9 million. The increase is also related to in higher employee costs, which increased by approximately $12.5 million, and commercial, marketing and other general and administrative costs increased by approximately $2.4 million. As of December 31, 2025, there was accounts receivable balance of approximately $4.2 million, whereas in the previous year period it was $0.

Cash used in investing activities

Cash used in investing activities increased by $266,788 to $293,489 for the year ended December 31, 2025 from $26,701 compared to the comparative period. During the year ended December 31, 2025, investing activities consisted of acquiring computer equipment and software.

Cash provided by financing activities

Cash provided by financing activities for the year ended December 31, 2025, decreased by $16,636,901 compared to the comparative period. During the year ended December 31, 2025, financing activities primarily consisted of raising net proceeds of $37,701,830 from stock and pre-funded warrants issued for cash, proceeds of $1,384,066 from the exercise of options and warrants, principal repayment of the promissory note of $911,463 and receiving $174,675 in government grant proceeds offset by $134,146 of related grant expenses. During the year ended December 31, 2024, financing activities primarily consisted of raising proceeds of $56,541,384 from stock and units issued for cash, proceeds $4,545,000 from the issuance of convertible debentures offset by issuance costs of $459,360, proceeds of $300,000 from the exercise of warrants and receiving $373,825 in government grant proceeds offset by $446,366 of related expenses.

Contractual Obligations and Other Commitments

In the normal course of business, we enter into agreements with contract service providers to assist in the performance of R&D and clinical and commercial manufacturing activities. We currently have three license agreements, the CMSI License Agreement, ALPHA-1062 technology and ALPHA-602 technology, which are outlined below. We expect to enter into additional clinical development, contract research, clinical and commercial manufacturing, supplier, and collaborative research agreements in the future, which may require upfront payments and long-term commitments of capital resources.

See "Note 14 – Commitments and Contingencies" of the accompanying consolidated financial statements for a discussion of our contractual obligations and long-term commitments.

Contingencies

The Company did not have any contingencies as of December 31, 2025, or the date of this report.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with US GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the consolidated financial statements and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We consider an accounting estimate to be critical if (i) it requires significant judgment and the use of assumptions about matters that are inherently uncertain, and (ii) changes in those assumptions could have a material impact on our consolidated financial statements.

The following are the accounting estimates that we believe are most critical to understanding our financial condition and results of operations.

Revenue Recognition, Including Variable Consideration

We generate revenue from product sales and licensing arrangements. Revenue is recognized when control of promised goods or services is transferred to customers in an amount that reflects the consideration we expect to receive. For product sales, revenue is recorded net of variable consideration, including estimated rebates, chargebacks, discounts, returns and other allowances.

Significant judgment is required in (i) estimating variable consideration, particularly given the early stage of commercialization of ZUNVEYL, (ii) determining standalone selling prices in licensing arrangements, and (iii) assessing performance obligations and allocation of transaction price. These estimates require the use of assumptions related to payer mix, contractual terms, product returns, and market adoption. Given our limited commercialization history, these estimates may be subject to increased variability, and changes in assumptions could materially impact revenue in future periods.

Fair Value of Warrant, Option, and Derivative Liabilities

Certain freestanding warrants and stock options are accounted for as liabilities and are remeasured at fair value at each reporting period, with changes recognized in the consolidated statement of operations and comprehensive loss. In addition, previously outstanding convertible instruments included embedded derivatives that required fair value measurement.

Significant judgments required in estimating the fair value of these financial instruments and embedded derivatives include (i) the selected valuation technique, (ii) volatility assumptions, and (iii) expected term. Changes in these assumptions can result in significant non-cash gains or losses in the consolidated statement of operations and comprehensive loss.

Stock-Based Compensation

We measure stock-based compensation based on the fair value of equity awards granted to employees and non-employees. The determination of fair value requires significant estimates, including (i) expected volatility of our common stock, (ii) expected term of awards, (iii) for certain awards, classification between equity and liabilities. Changes in these assumptions could materially impact the amount and timing of compensation expense recognized.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to opt out of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. We will continue to remain an emerging growth company until the earliest of the following: (1) December 31, 2029; (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 billion; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting Common Stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting Common Shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLSOURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Report of Independent Registered Public Accounting Firm, our consolidated financial statements and accompanying notes listed under Part IV, Item 15. Exhibits, Financial Statement Schedules of this Annual Report on Form 10-K are set forth beginning on page F-1 immediately following the signature page hereof and incorporated by reference herein.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

In connection with our change in accountants during the fiscal year ended December 31, 2025, there were not any disagreements with our former accountant on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, or any reportable event as described in paragraph (a)(1)(v) of Item 304 of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

At the end of the period covered by this annual report on Form 10-K for the fiscal year ended December 31, 2025, an evaluation was carried out under the supervision of and with the participation of our management, including the Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), of the effectiveness of the design and operations of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act). Based on that evaluation, the CEO and the CFO have concluded that as of the end of the period covered by this annual report, our disclosure controls and procedures were not effective in ensuring that: (i) information required to be disclosed by us in reports that we file or submit to the SEC under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms and (ii) material information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow for accurate and timely decisions regarding required disclosure.

Management determined that disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting, as described below, which required us to correct certain accounting items in our audited financial statements.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework* (2013 Framework).

Based on this assessment and due to the material weaknesses described below, management concluded that our internal control over financial reporting ineffective as of December 31, 2025.

Material Weaknesses and Plan to Remediate

The material weakness identified is a result of a lack adequate procedures to appropriately account for accounting transactions including warrants and stock option liabilities, certain deferred tax disclosures, and a lack of segregation of duties due to the size of the finance and accounting team.

We plan to remediate the material weakness by enhancing our system of internal control over financial reporting, including, but not limited to, engaging external technical accounting experts to advise and review all complex accounting transactions, ensuring appropriate analysis, documentation, and oversight prior to the finalization of our financial statements, implementing an accounting standards compliance process to ensure timely adoption and assessment of evolving accounting standards, and strengthening financial disclosure resources those involving the third-party valuation specialist. Although we are committed to continuing to improve our internal control processes and intend to remediate our material weaknesses, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives.

Changes in Internal Control over Financial Reporting

Other than the ongoing steps being taken to implement the remediation plan described above, there has been no other changes in our internal control over financial reporting during the quarter ended December 31, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

(a) None.

(b) During the quarter ended December 31, 2025, none of our directors or officers adopted, modified, or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement (the "Proxy Statement") to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. Executive Compensation.

The information required by this Item 11 will be included in our Proxy Statement and is incorporated herein by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in the Security Ownership of Certain Beneficial Owners and Management sections of our Proxy Statement and is incorporated herein by reference.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our Proxy Statement and is incorporated herein by reference.

ITEM 14. Principal Accountant Fees and Services.

Our independent public accounting firm is CBIZ CPAs P.C. New York, New York, USA, PCAOB Auditor ID: 199.

The information required by this Item 14 will be included in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS SCHEDULES

(1). **Financial Statements**. The Report of Independent Registered Public Accounting Firm, our consolidated financial statements and accompanying notes are set forth beginning on page F-1 immediately following the signature page of this Form 10-K.

(2). **Financial Statement Schedules**. Financial Statement Schedules are omitted because the information required is not applicable or the required information is shown in the financial statements or notes thereto.

(3) **Exhibits**. The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	Notice of Articles, previously filed as Exhibit 3.1 to the Company's Form S-1 filed with the SEC on June 14, 2024 and incorporated herein by reference (File No. 333-280196)
3.2	Articles, previously filed as Exhibit 3.1 to the Company's Form 8-K filed with the SEC on October 3, 2024 and incorporated herein by reference (File No. 333-280196)
4.1	Specimen common share certificate, previously filed as Exhibit 4.1 to the Company's Form S-1 filed with the SEC on June 14, 2024 and incorporated herein by reference (File No. 333-280196)
42	Escrow Agreement by and between the Company, Computershare Investor Services Inc. and certain stockholders of the Company dated March 18, 2021, previously filed as Exhibit 4.2 to the Company's Form S-1 filed with the SEC on June 14, 2024 and incorporated herein by reference (File No. 333-280196)
4.3	Form of Warrant issued September 24, 2024, previously filed as Exhibit 10.3 to the Company's Form 8-K filed with the SEC on September 25, 2024 and incorporated herein by reference (File No. 333-280196)
4.4	Form of Convertible Note issued September 24, 2024, previously filed as Exhibit 10.2 to the Company's Form 8-K filed with the SEC on September 25, 2024 and incorporated herein by reference (File No. 333-280196)
4.5	Form of Pre-Funded Warrant, previously filed as Exhibit 4.5 to the Company's Form S-1/A filed with the SEC on October 25, 2024 and incorporated herein by reference (File No. 333-280196)
4.6	Form of Underwriters Warrant, previously filed as Exhibit 4.6 to the Company's Form S-1/A filed with the SEC on October 25, 2024 and incorporated herein by reference (File No. 333-280196)
4.7	Description of Registrant's Securities, previously filed as Exhibit 4.7 to the Company's Annual Report on Form 10-K on March 31, 2025 and incorporated herein by reference (File No. 001-42403)
10.1#	2017 Stock Option Plan, previously filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.2#	2022 Stock Option Plan, previously filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.3#	2023 Stock Option Plan, previously filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.4	ALPHA-1062 License Agreement dated March 23, 2015, as amended effective April 1, 2015 between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.5	ALPHA-1062 Royalty Assignment Agreement dated January 1, 2016 between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.6	ALPHA-0602 License Agreement dated January 1, 2020, as amended November 4, 2020 between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.7	ALPHA-0602 Royalty Agreement dated November 3, 2020 between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.8	Arrangement Agreement dated October 27, 2020, between the Company and Alpha Cognition, Inc, as amended, pursuant to which the Company acquired all of the issued and outstanding shares of Alpha Cognition, Inc pursuant to a plan of arrangement which constituted the Company's Qualifying Transaction, previously filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.9	Agency Agreement dated December 18, 2020 among the Company, Alpha Cognition, Inc and Raymond James & Associates Inc., pursuant to which the Company and Alpha Cognition, Inc issued subscription receipts that were converted into Common Shares and Warrants upon completion of the Qualifying Transaction, previously filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.10	Escrow Agreement dated March 18, 2021 between the Company, Computershare Investor Services Inc., and certain shareholders of the Company, previously filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)

10.11	Consulting Agreement between the Company and CMI Cornerstone Management Corporation dated September 1, 2018 as amended June 1, 2019, previously filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.12	Expense Reimbursement Promissory Note dated December 31, 2017 by and between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1/A as filed with the SEC on May 10, 2024 and incorporated herein by reference (File No. 333-280196)
10.13	Investment Banking Agreement between the Company and Spartan Capital Securities, LLC dated May 17, 2023, previously filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.14	Amendment No. 1 to Investment Banking Agreement between the Company and Spartan Capital Securities, LLC dated December 4, 2023, previously filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.15	Consulting Agreement between the Company and Spartan Capital Securities, LLC dated May 17, 2023, previously filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.16	APLHA-1062 Second Amended License Agreement dated March 1, 2023 between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.17	Second Amended Expense Reimbursement Promissory Note dated March 1, 2023 by and between the Company and Neurodyn Life Sciences Inc., previously filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.18#	Employment Agreement between the Company and Michael McFadden dated March 28, 2022, previously filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.19#	Bonus Right Agreement by and between the Company and Michael McFadden dated April 28, 2022, previously filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.20#	Employment Agreement by and between the Company and Lauren D'Angelo dated May 1, 2021, previously filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.21#	Amendment #1 to Employment Agreement by and between the Company and Lauren D'Angelo dated June 22, 2022, previously filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.22#	Amendment to Employment Agreement by and between the Company and Lauren D'Angelo dated March 1, 2023, previously filed as Exhibit 10.24 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.23#	Bonus Right Agreement by and between the Company and Lauren D'Angelo dated May 10, 2022, previously filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.24	Registration Rights Agreement dated September 24, 2024, previously filed as Exhibit 10.1 to the Company's Form 8-K as filed with the SEC on September 25m 2024 and incorporated herein by reference (File No. 001-42403)
10.25**	Securities Purchase Agreement dated September 24, 2024, previously filed as Exhibit 10.2 to the Company's Form 8-K as filed with the SEC on September 25m 2024 and incorporated herein by reference (File No. 001-42403)
10.26#	Employment Agreement, dated as of October 21, 2024, by and between Alpha Cognition USA Inc. and Henry Du, previously filed as Exhibit 10.24 to the Company's Registration Statement on Form S-1 as filed with the SEC on April 30, 2024 and incorporated herein by reference (File No. 333-280196)
10.27	Agreement and Waiver to the Investment Banking Agreement dated June 10, 2024, previously filed as Exhibit 10.1 to the Company's Form 8-K filed with the SEC on June 14, 2024 and incorporated herein by reference (File No. 333-280196)
10.28	Underwriting Agreement, dated November 13, 2024, previously filed as Exhibit 1.1 to the Company's Form 8-K filed with the SEC on November 18, 2024, and incorporated herein by reference (File No. 001-42403)

10.29	Underwriting Agreement, dated September 30, 2025, previously filed as Exhibit 1.1 to the Company's Form 8-K filed with the SEC on October 2, 2025, and incorporated herein by reference (File No. 001-42403)
10.30	At the Market Offering Agreement, dated August 22, 2025, by and between the Company and H.C. Wainwright & Co., LLC previously filed as Exhibit 1.2 to the Company's Registration Statement on Form S-3 as filed with the SEC on August 22, 2025 and incorporated herein by reference (File No. 333-289792)
10.31#	2025 Stock Incentive Plan previously filed as Appendix B of the Company's Schedule 14A Definitive Proxy Statement as filed with the Commission on April 30, 2025and incorporated herein by reference (File No. 001-42403)
19	Alpha Cognition Insider Trading Policy, previously filed as Exhibit 19 to the Company's Form 10-K filed with the SEC on March 31, 2025 and incorporated herein by reference (File No. 001-42403)
21	Subsidiaries of the Company, previously filed as Exhibit 21 to the Company Form 10-K filed with the SEC on March 31, 2025 and incorporated herein by reference (File No. 001-42403)
23.1	Consent of CBIZ CPAs P.C.
23.2	Consent of Manning Elliott
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97*	Alpha Cognition Incentive Compensation Recovery Policy, previously filed as Exhibit 97 to the Company Form 10-K as filed with the SEC on March 31, 2025 and incorporated herein by reference (File No. 001-42403)
101.INS(1)	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH(1)	XBRL Taxonomy Extension – Schema
101.CAL(1)	XBRL Taxonomy Extension – Calculations
101.DEF(1)	XBRL Taxonomy Extension – Definitions
101.LAB(1)	XBRL Taxonomy Extension – Labels
101.PRE(1)	XBRL Taxonomy Extension – Presentations
104	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Filed herewith

\# Indicates management contract or compensatory plan

** Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request

(1) Submitted electronically herewith. Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Statements of Income (Loss) for the fiscal years ended December 31, 2025 and 2024, (ii) Consolidated Balance Sheets at December 31, 2025 and December 31, 2024, (iii) Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024, and (iv) Notes to Consolidated Financial Statements.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the *Securities Exchange Act of 1934*, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALPHA COGNITION INC.
(Registrant)

Dated: March 31, 2026

By: /s/ *Michael McFadden*
Michael McFadden,
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Capacity	Date
/s/ *Michael McFadden* Michael McFadden	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2026
/s/ *Henry Du* Henry Du	Vice President of Finance and Accounting and interim Chief Financial Officer (Principal Accounting and Financial Officer)	March 31, 2026
/s/ *Len Mertz* Len Mertz	Director	March 31, 2026
/s/ *Kenneth Cawkell* Kenneth Cawkell	Director	March 31, 2026
/s/ Robert Wills Robert Wills	Director	March 31, 2026
/s/ Phillip Mertz Phillip Mertz	Director	March 31, 2026
/s/ Rajeev Bakshi Rajeev Bakshi	Director	March 31, 2026

ALPHA COGNITION INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements as of and for the Years Ended December 31, 2025 and 2024:

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Alpha Cognition, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Alpha Cognition, Inc. (the "Company") as of December 31, 2025, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficiency) and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2025

San Diego, California
March 31, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors Alpha Cognition Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Alpha Cognition Inc. and its subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficiency) and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

CHARTERED PROFESSIONAL ACCOUNTANTS

/s/ Manning Elliott LLP

Vancouver, Canada

March 31, 2025, except as to Note 2A, as to which the date is March 31, 2026

We have served as the Company's auditor since 2019

ALPHA COGNITION INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 66,046,789	$ 48,546,210
Restricted cash	58,400	17,872
Accounts receivable, net	4,236,136	-
Inventory	5,123,496	615,133
Prepaid expenses and other current assets	3,545,451	1,071,963
Total current assets	79,010,272	50,251,178
Other assets	-	45,714
Equipment, net	328,540	27,077
Intangible assets, net	391,423	412,969
Total assets	**$ 79,730,235**	**$ 50,736,938**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 8,976,904	$ 2,439,289
Current portion of promissory note - related party	-	911,463
Current deferred income	153,171	-
Total current liabilities	9,130,075	3,350,752
Deferred income	35,944	-
Option liabilities	3,174,662	2,368,218
Warrant liabilities	4,812,198	5,820,358
Other long-term liabilities	47,181	102,783
Total liabilities	17,200,060	11,642,111
Stockholders' equity		
Common stock, no par value, unlimited stock authorized, 21,742,104 and 16,019,787 shares issued and outstanding as of December 31, 2025, and December 31, 2024, respectively	133,891,673	99,128,230
Class B preferred stock, no par value, unlimited stock authorized, 316,655 shares issued and outstanding as of December 31, 2025 and December 31, 2024	62	62
Additional paid-in capital	25,849,516	16,507,736
Accumulated other comprehensive loss	(104,301)	(104,301)
Accumulated deficit	(97,106,775)	(76,436,900)
Total stockholders' equity	62,530,175	39,094,827
Total liabilities and stockholders' equity	**$ 79,730,235**	**$ 50,736,938**

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

ALPHA COGNITION INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2025	**2024**
Revenue		
Product, net	$ 6,792,024	$ -
Licensing	3,428,251	-
Total revenue	10,220,275	-
Operating Expenses		
Cost of product sales, excluding amortization of intangible asset	474,006	-
Cost of licensing revenue	1,441,317	-
Amortization of intangible asset	21,546	79,875
Research and development	1,867,972	3,920,412
Selling, general and administrative expenses	29,076,123	8,012,230
Total operating expenses	32,880,964	12,012,517
Loss from operations	(22,660,689)	(12,012,517)
Other income (expenses)		
Interest income	1,899,370	161,664
Grant income	81,095	463,881
Gain (loss) on derivative liabilities and conversion of convertible debt	88,155	(3,164,707)
Other expenses	(77,806)	(237,048)
Total other income (expenses)	1,990,814	(2,776,210)
Net loss and comprehensive loss	$ (20,669,875)	$ (14,788,727)
Weighted average stock outstanding, basic	17,680,597	7,247,864
Net loss per share, basic	$ (1.17)	$ (2.04)
Adjusted net loss, diluted	$ (20,846,806)	$ (14,788,727)
Weighted average stock outstanding, diluted	17,681,429	7,247,864
Net loss per share, diluted	$ (1.18)	$ (2.04)

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

ALPHA COGNITION INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

For the year ended December 31, 2025

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance, December 31, 2024	**16,019,787**	**$ 99,128,230**	**316,655**	**$ 62**	**$16,507,736**	**$ (104,301)**	**$ (76,436,900)**	**$ 39,094,827**
Stock issued for cash, net	5,491,516	32,132,229	-		-	-	-	32,132,229
Warrants issued for cash, net	-	-	-		5,569,601	-	-	5,569,601
Options exercised	89,801	708,508	-		(624)	-	-	707,884
Warrants exercised	141,000	1,922,706	-	-	-	-	-	1,922,706
Stock-based compensation	-	-	-	-	3,772,803	-	-	3,772,803
Net loss	-	-	-	-	-	-	(20,669,875)	(20,669,875)
Balance, December 31, 2025	**21,742,104**	**$133,891,673**	**316,655**	**$ 62**	**$25,849,516**	**$ (104,301)**	**$ (97,106,775)**	**$ 62,530,175**

For the Year Ended December 31, 2024

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance, December 31, 2023	**4,728,355**	**$39,760,287**	**316,655**	**$ 62**	**$17,288,430**	**$ (104,301)**	**$ (61,648,173)**	**$ (4,703,695)**
Units issued for cash	678,630	3,732,469	-	-	-	-	-	3,732,469
Stock issued for cash	9,184,159	52,808,915	-	-	-	-	-	52,808,915
Stock issued for conversion of convertible debentures and interest	801,412	4,609,388	-	-	-	-	-	4,609,388
Stock issued for services	413,445	2,273,949						2,273,949
Stock issuance costs	168,886	(8,777,757)	-	-	582,245	-	-	(8,195,512)
Options exercised	14,900	128,182	-	-	(126,382)	-	-	1,800
Warrants exercised	30,000	300,000	-	-	-	-	-	300,000
Stock-based compensation	-	-	-	-	831,735	-	-	831,735
Recognition of CAD Option Liabilities	-	-	-	-	(2,068,292)	-	-	(2,068,292)
Reallocation of derivative liability on re-pricing of warrants from CAD to USD exercise price	-	4,292,797	-	-	-	-	-	4,292,797
Net loss	-	-	-	-	-	-	(14,788,727)	(14,788,727)
Balance, December 31, 2024	**16,019,787**	**$99,128,230**	**316,655**	**$ 62**	**$16,507,736**	**$ (104,301)**	**$ (76,436,900)**	**$ 39,094,827**

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

ALPHA COGNITION INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2025	**2024**
Cash flows used in operating activities		
Net loss	$ (20,669,875)	$ (14,788,727)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	58,572	81,220
Accrued expenditures for government grant	53,051	(17,515)
Accrued interest	-	65,996
Accrued interest income, related party	-	2,550
Loss (gain) on derivative liabilities and conversion of convertible debt	(88,155)	3,164,707
Change in fair value of bonus rights liability	(55,602)	18,658
Non-cash debt issuance costs	-	459,360
Provision for loan losses	-	55,000
Impairment of intangible assets	-	39,166
Loss on disposal of equipment	18,000	-
Stock-based compensation	4,922,525	1,131,661
Shares issued for services	-	2,273,949
Changes in non-cash operating working capital items:		
Accounts receivable, net	(4,236,136)	-
Inventories	(4,508,363)	(615,133)
Prepaid expenses and other current assets	(2,490,774)	(671,718)
Accounts payable and accrued liabilities	6,520,855	1,045,172
Deferred income	95,535	-
Net cash used in operating activities	(20,380,367)	(7,755,654)
Cash flows used in investing activities		
Acquisition of equipment	(293,489)	(26,701)
Net cash used in investing activities	(293,489)	(26,701)
Cash flows provided by financing activities		
Units issued for cash	-	3,732,469
Stock issued for cash	34,321,975	52,808,915
Stock issuance costs	(2,547,222)	(5,704,419)
Warrants issued for cash	5,927,077	-
Exercise of options	364,606	1,800
Exercise of warrants	1,019,461	300,000
Repayment of promissory notes	(911,463)	(300,000)
Proceeds received from restricted government grant	174,675	373,825
Amounts paid from restricted government grant funds	(134,146)	(446,366)
Proceeds from the issuance of convertible debentures	-	4,545,000
Debt issuance costs	-	(459,360)
Net cash provided by financing activities	38,214,963	54,851,864
Change in cash, cash equivalents, and restricted cash during the year	17,541,107	47,069,509
Cash, cash equivalents, and restricted cash beginning of year	48,564,082	1,494,573
Cash, cash equivalents, and restricted cash end of year	**$ 66,105,189**	**$ 48,564,082**

ALPHA COGNITION INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2025	**2024**
Supplemental Disclosure		
Cash paid for interest	**$ 4,894**	**$ 37,754**
Supplemental non-cash disclosures		
Reallocation of fair value of share options upon exercise	**$ 410,585**	**$ 126,832**
Reclassification of derivative liability of warrants exercised	**$ 903,245**	**$ -**
Reclassification of derivative liability for warrants re-priced from CAD to USD exercise price	**$ -**	**$ 4,292,797**
Recognition of Option liabilities	**$ -**	**$ 2,068,292**
Common shares issued for share issuance costs	**$ -**	**$ 928,874**
Warrants issued for share issuance costs	**$ -**	**$ 3,073,338**
Common shares issued for services	**$ -**	**$ 2,273,949**

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

NOTE 1 – NATURE OF OPERATIONS

Alpha Cognition Inc. ("ACI" or the "Company") is a commercial stage, 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 focuses on the commercial manufacturing and commercial sales of its ZUNVEYL oral tablet formulation, which was launched on March 19, 2025. The Company's commercial program for ZUNVEYL is primarily focused on its long-term care commercial team that can focus on providing key points of differentiation, exploiting key issues with existing AChEI treatments, and franchising potential additional indications and new products. As of November 12, 2024, the Company's common shares commenced trading on the NASDAQ stock exchange under the symbol "ACOG". The Company's common shares traded on the Canadian Securities Exchange ("CSE") under the symbol "ACOG" from May 1, 2023 to December 17, 2024 on which date they were voluntarily delisted.

On November 5, 2024, the Company completed a reverse stock split on the ratio of one share issued for every previously issued and outstanding twenty-five shares. All current and comparative references to the number and price per share for common shares, preferred shares, options, warrants, ACI Canada legacy performance options and weighted average number of shares, loss per share, have been restated to give effect to this reverse stock split.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Note 2A Revisions to Previously Issued Consolidated Financial Statements and Financial Information –

During the preparation of its consolidated financial statements for the year ended December 31, 2025, the Company identified an error in its previously reported consolidated financial statements for the year ended December 31, 2024. Specifically, certain options denominated in Canadian dollars (the "CAD Options") were previously classified as equity awards. Upon further evaluation of the terms of the CAD Options and the applicable accounting guidance, the Company determined that because the exercise price of the CAD Options is denominated in a currency that is different than the one in which a substantial portion of the Company's shares are traded, the CAD Options are considered to be indexed to a factor other than a market, performance, or service condition. Accordingly, the CAD Options should have been classified as liability-classified awards measured at fair value beginning with the Company's US initial public offering in November 2024, with subsequent changes in fair value recognized in earnings each reporting period.

In accordance with Staff Accounting Bulletin ("SAB") 99, Materiality, and SAB 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in the Current Year Financial Statements, the Company evaluated the materiality of the error from qualitative and quantitative perspectives, and concluded that the error was immaterial to any prior annual or interim financial statements.

However, the Company has corrected the error in the current year comparative consolidated financial statements by adjusting the information, as applicable, as of and for the fiscal year ended December 31, 2024. A summary of the corrections to the affected financial statement line items in these consolidated financial statements is presented below.

Consolidated Balance Sheets

	December 31, 2024		
	As Reported	Adjustment	As Revised
Long term liabilities			
Option liabilities	$ -	$ 2,368,218	$ 2,368,218
Total liabilities	$ 9,273,893	$ 2,368,218	$ 11,642,111
Stockholders' equity			
Additional paid-in capital	$ 18,724,092	$ (2,216,356)	$ 16,507,736
Accumulated deficit	(76,285,038)	(151,862)	(76,436,900)
Total stockholders' equity	41,463,045	(2,368,218)	39,094,827
Total liabilities and stockholders' equity	$ 50,736,938	$ -	$ 50,736,938

Consolidated Statements of Operations and Comprehensive Loss

	Fiscal Year Ended December 31, 2024		
	As Reported	Adjustment	As Revised
Operating expenses			
Research and development	$ 3,918,543	$ 1,869	$ 3,920,412
General and administrative expenses	$ 7,942,112	$ 149,993	$ 8,092,105
Total operating expenses	$ 11,860,655	$ 151,862	$ 12,012,517
Net operating loss	$ (11,860,655)	$ (151,862)	$ (12,012,517)
Total other income (expenses)	$ (2,776,210)	$ -	$ (2,776,210)
Net loss	$ (14,636,865)	$ (151,862)	$ (14,788,727)
Comprehensive loss	$ (14,636,865)	$ (151,862)	$ (14,788,727)
Net loss per share, basic and diluted	$ (2.02)	$ (0.02)	$ (2.04)

Consolidated Statements of Cash Flows

	Fiscal Year Ended December 31, 2024		
	As Reported	Adjustment	As Revised
Net loss	$ (14,636,865)	$ (151,862)	$ (14,788,727)
Cash flow used in operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	$ 979,799	$ 151,862	$ 1,131,661

The Company will also revise previously reported quarterly financial information for the identified error based on the summary presented herein in its future filings with the SEC, as applicable. A summary of the corrections to the affected financial statement line items to the Company's previously issued condensed consolidated financial statements for each quarterly period is presented in Note 18 of the notes to the consolidated financial statements.

Note 2B

Basis of Presentation – The accompanying consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

Principles of Consolidation – These consolidated financial statements include the accounts of the Company, its wholly owned subsidiary, Alpha Cognition Canada Inc. ("ACI Canada") and ACI Canada's wholly owned subsidiary Alpha Cognition USA Inc. ("ACI USA"). All significant intercompany accounts and transactions between the Company and its subsidiaries have been eliminated upon consolidation.

Functional and Reporting Currency – The functional currency of an entity is the currency of the primary economic environment in which the entity operates. The functional currency of the Company and each of its subsidiaries is the United States Dollar ("USD"). The Company's consolidated reporting currency is USD and, unless specifically noted otherwise, all amounts presented are in USD. Foreign currency differences that arise from translating a subsidiary's financial statements to USD are recognized in other comprehensive loss on the consolidated statements of operations and comprehensive loss.

Liquidity - The Company does not have sufficient operating revenue to finance its existing obligations and has relied on external financing, such as debt and equity raises, to generate capital to maintain its capacity to meet working capital requirements. The Company has successfully raised funds that exceed the Company's working capital requirements for the next 12 months from the date of issuance of these consolidated financial statements. The Company expects to continue to rely on debt and the issuance of shares, and possibly other non-dilutive financing options to finance its ongoing operations and plans for commercialization of ZUNVEYL. However, there is a risk that additional financing will not be available on a timely basis or on terms acceptable to the Company.

Use of Estimates and Assumptions – The preparation of these consolidated financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and disclosure of contingent liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The Company's most significant estimates relate to the fair value of its warrant liabilities, CAD Options liability, and stock option grants, and its estimates of the standalone selling prices of certain performance obligations. On an ongoing basis, management evaluates its estimates, to ensure that those estimates effectively reflect changes in the Company's business and new information as it becomes available. Management bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to forecasted amounts and future events. Actual results could differ materially from these estimates under different assumptions or conditions.

Concentrations of Credit and Supply Risk – The Company's financial instruments subject to concentrations of credit risk consists primarily of cash and cash equivalents and accounts receivable. Cash is deposited with financial institutions with high credit quality which are typically in excess of insured limits. During the year ended December 31, 2025, and 2024, the Company did not experience any loss related to these concentrations.

The Company considers its significant customers to be those that represent more than 10% of total revenue or accounts receivable. As of and for the year ended December 31, 2025, the Company had three customers that accounted for approximately 48%, 22% and 17% of total revenue and these three same customers that accounted for 60%, 17% and 19% of accounts receivable, respectively. As of and for the year ended December 31, 2024, the Company had no significant customers.

The Company relies on a single, Taiwan-based vendor for the supply of its active pharmaceutical ingredient ("API") and a single, U.S.-based vendor for the manufacture of ZUNVEYL. The Company does not have long-term supply agreements with these vendors, or such agreements may be terminable by the vendor upon limited notice. As a result, the Company is exposed to supply interruption risk in the event that these vendors experience operational, regulatory, financial, or other difficulties, or otherwise fail to meet the Company's quality, quantity, or timing requirements. The loss of, or a significant disruption in, supply from these vendors, or the Company's inability to obtain alternative sources of API or manufacturing services on commercially reasonable terms and within required timelines, could have a material adverse effect on the Company's ability to manufacture and supply its products, which could adversely impact its business, results of operations, and financial condition.

Cash and Cash Equivalents – The Company considers cash to include currency on hand, demand deposits with banks or other financial institutions, and other kinds of accounts that have the general characteristics of demand deposits in that the Company may deposit additional funds at any time and also effectively may withdraw funds at any time without prior notice or penalty. The Company considers cash equivalents to include term deposits, certificates of deposit, and all highly liquid instruments with original maturities of three months or less.

Inventory – The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing costs, on a first-in, first-out basis. The Company classifies inventory as long-term when consumption or sale of the inventory is expected beyond its normal operating cycle of twelve months. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required which would be recorded as cost of sales in the consolidated statements of operations.

The Company began to capitalize inventory costs related to ZUNVEYL following receipt of regulatory approval in July 2024. Prior to this, inventory costs were expensed as research and development expense as incurred. Raw materials capitalized in inventory consist of materials, including active pharmaceutical ingredients, to be consumed in production of inventory related to FDA approved products.

Equipment – Equipment is stated at historical cost less accumulated depreciation. Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized in the consolidated statement of operations. Repairs and maintenance are expensed as incurred. Depreciation is charged over the estimated useful lives using the straight-line method as follows:

Computer equipment	3 years
Computer software	3 years
Construction in progress	Not depreciated

Intangible Assets – The Company's intangible assets consist of exclusive licenses that allow the Company to further develop and exploit the ALPHA-1062 and ALPHA-0602 Technology described in Note 16. The licenses are carried at cost and amortized on a straight-line basis over their estimated useful life of 15 years. During the year ended December 31, 2024, the Company wrote off the ALPHA-0602 licenses in the amount of $39,166 on the consolidated statements of operations and comprehensive loss.

Leases – The Company does not recognize a right of use asset or corresponding lease liability for any lease that, at the commencement date, has a term of 12 months or less and does not include an option to renew the lease or purchase the underlying asset that the Company is reasonably certain to exercise. Instead, the total cash payments due under a short-term lease are expensed on a straight-line basis over the term of the lease. During the years ended December 31, 2025 and 2024, all of the Company's leases were short-term leases.

Impairment of Long-Lived Assets – The Company reviews long-lived assets, primarily comprised of equipment and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If the carrying value of such assets are considered to not be recoverable, an impairment loss is recognized equal to the amount by which the carrying value of the long-lived asset exceeds its fair value. The Company did not identify any indicators of impairment in 2025. During the year ended December 31, 2024, the Company recorded $39,166 of impairment related to its ALPHA-0602 licenses intangible asset.

Convertible Debentures and Conversion Feature Liability – The Company's convertible debentures, which were converted into shares of common stock in November 2024, contained a host liability and an embedded conversion feature that required bifurcation (see Note 7). As such, the embedded conversion feature was initially recorded at fair value and then will be remeasured to fair value each reporting period and on settlement with the change recognized as a gain or loss in the consolidated statements of operations and comprehensive loss.

Warrant Liabilities – As described in Note 9, certain freestanding warrants to purchase common stock are accounted for as liabilities. As such, the estimated fair value of each warrant will be remeasured at the end of each reporting period and on settlement and the change is recognized as a gain or loss in the consolidated statements of operations and comprehensive loss.

Revenue Recognition – Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company applies the following five-step revenue recognition model in accordance with ASC Topic 606, Revenue from Contracts with Customers, to determine revenue:

i) identify the contract with a customer;

ii) identify the performance obligations in the contract;

iii) determine the transaction price;

iv) allocate the transaction price to the performance obligations in the contract; and

v) recognize revenue when (or as) the Company satisfies a performance obligation.

At contract inception, the Company identifies the goods or services promised in the contract and assesses whether each is distinct for the purpose of identifying performance obligations. A promised good or service is distinct if (1) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer; and (2) the Company's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company evaluates whether such options provide a material right to the customer. If so, they are treated as separate performance obligations.

The transaction price of a customer contract is determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP"). SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Judgment is required in estimating SSP, and the Company considers market conditions, entity-specific factors, and estimated costs in making this determination.

If the consideration includes a variable amount, the Company estimates the amount to which it expects to be entitled using either the expected value or the most likely amount method, depending on which better predicts the outcome. The estimated amount is included in the transaction price only to the extent it is probable that a significant reversal of cumulative revenue will not occur when the uncertainty is resolved. The Company re-evaluates estimates and constraints at each reporting date and adjusts the transaction price accordingly, recording any changes on a cumulative catch-up basis.

Revenue is recognized when the Company satisfies a performance obligation, either at a point in time or over time. The amount of revenue recognized is based on the portion of the transaction price allocated to each performance obligation in accordance with its relative SSP. For obligations satisfied over time, revenue is recognized using an input or output method, depending on which most accurately depicts the transfer of control to the customer.

Product Sales, Net

Products are primarily sold to direct customers such as wholesalers and pharmacies. The Company's contractual performance obligations are generally limited to the transfer of control of the product to the customer. For ZUNVEYL tablets provided to customers, revenue is recognized at the point in time when control of the goods transfers to the customer. The Company's contracts typically stipulate F.O.B. (Free on Board) destination terms. Consequently, revenue is recognized when the drugs are delivered to the customer's location or any destination designated by the customer for drop-shipment. This arrangement is not a consignment arrangement, and therefore, the Company recognizes revenue upon the delivery of goods to the customer. The Company's payment terms to customers range from 30 to 68 days; payment terms differ by customer.

Revenue from the Company's product sales is reduced for expected prompt pay discounts, chargebacks, product returns, recalls, rebates, and consideration payable to customers, collectively referred to as gross-to-net (GTN) adjustments. Estimates of GTN adjustments are based various factors such as historical experience, projected market conditions, production expiration dates, analogs and the specific terms of the Company's agreements with payers and customers. Variable consideration is re-evaluated at least on a quarterly basis and typically monthly. The amount of variable consideration can vary from period to period due to fluctuations in GTN components.

Consideration payable to customers includes fees paid to distributors that are calculated as a percentage of monthly product sales based on the Wholesale Acquisition Cost (WAC). These fees are paid to distributor customers for services such as access to inventory and sales data to pharmacies, inventory management, accounts receivable administration, and return and chargeback administration. Fees paid to distributors for services that are integral activities within the distribution chain with the customer, specifically related to the Company's sales of ZUNVEYL, are recognized as a reduction of revenue since these activities are not considered distinct from the Company's promise to sell ZUNVEYL through the distribution channel to end customers. Fees paid to customers for services that transfer a distinct service to the Company, such as logistics services, are recorded as operating expenses.

Licensing Revenue

In licensing arrangements, the identification of performance obligations considers factors such as the partner's capabilities and the availability of required expertise in the marketplace. The intended benefit of the contract is also considered in determining whether a promised good or service is separately identifiable. If a good or service is not distinct, it is combined with other promised goods or services until a distinct bundle is identified.

For arrangements that include development or regulatory milestone payments, the Company evaluates whether achieving the milestone is probable and recognizes revenue only if a significant reversal is not expected. Regulatory milestones that are outside the control of either party are generally excluded from the transaction price until achieved.

For licenses of intellectual property that include sales-based royalties or milestones, and when the license is the predominant item to which the royalties relate, the Company recognizes royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied, consistent with the sales-based royalty exception.

Accounts Receivable - The majority of the accounts receivable arise from product sales and primarily represent amounts due from our wholesale and other third-party distributors. The Company's standard payment terms generally require payment within 30 to 68 days.

Accounts receivable, which are uncollateralized, are carried at their original cost less an allowance for credit losses that reflects the Company's estimate of expected lifetime credit losses from these receivables. To estimate expected credit losses, the Company applies an expected rate of loss that is determined using historical credit loss information that is adjusted for expectations of future losses based on current and projected changes, if any, to the Company's mix of customers, macroeconomic conditions, and industry-specific factors that may impact future collection rates. Past due accounts receivable balances are written off when the Company's internal efforts have been unsuccessful in collecting the amount due. The Company's allowance for doubtful accounts was $0 at December 31, 2025 and 2024.

Royalty Cost of Sales – The Company makes royalty payments to third parties under license or purchase agreements associated with the acquisition of intellectual property. These royalty payments are calculated as a percentage of the net product sales and licensing fees in the period the corresponding sales occur. Royalty expenses are recognized as incurred and recorded as a component of cost of sales in the consolidated statements of operations and comprehensive loss. During the years ended December 31, 2025 and 2024, the Company incurred royalty expenses of $1,030,028 and $0, respectively

Research and Development Costs – The Company expenses research and development costs as incurred. Advance payments for services that will be rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related services are performed.

Advertising Costs – The Company expenses advertising costs when incurred. During the years ended December 31, 2025 and 2024, the Company incurred advertising expenses of $380,774 and $97,535, respectively, which are classified as selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Share-Based Compensation – The Company measures the expense related to share-based awards at the fair value of those awards on the date of grant and recognizes this amount over the requisite service period of the individual grant, which is typically equal to the vesting period. If the requisite service is not rendered, the effect on share-based compensation expense is recognized in the period the award is forfeited.

The fair value of share-based awards is determined on the grant date using the Black-Scholes option pricing model. This model is affected by the Company's share price as well as assumptions regarding a number of subjective variables. These subjective variables include, but are not limited to, the Company's expected share price volatility over the terms of the awards, and actual and projected employee share option exercise behaviors. The Company records share-based compensation expense for service-based options on an accelerated attributions method over the requisite service period.

For share options with performance conditions, the Company records compensation expense only when it is deemed probable that the performance condition will be met. The Company records share-based compensation expense for performance-based share options on an accelerated attribution method over the requisite service period.

Liability-Based Awards – Bonus right awards that include cash settlement features are accounted for as liability-based awards in accordance with ASC 718, *Compensation – Share Based Compensation*. The fair value of the bonus right awards is estimated using a Black-Scholes option-pricing model and is revalued on each reporting date based on the probability of the expected awards to vest. Changes in the estimated fair value of the bonus right awards are recognized within selling, general and administrative expense in the consolidated statements of operations and comprehensive loss. Key assumptions in the calculation of the fair value of the bonus right awards include expected volatility, the risk-free interest rate, expected life, and fair value per award.

At both December 31, 2025 and 2024, the Company had 758,300 and 851,467 outstanding stock options, respectively, with exercises prices denominated in CAD. Because the exercise prices of these options are denominated in a currency that is different than the one in which a substantial portion of the Company's shares are traded, the CAD Options are considered to be indexed to a factor other than a market, performance, or service condition. As a result, the CAD Options are classified as liabilities and remeasured at fair value each reporting period with the corresponding change in fair value recorded as an increase or decrease in stock-based compensation expense within research and development and selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss

Grant Income and Expenses – All funds relating to government grants are recorded under the gross method of accounting for government grants whereby any income received is reported as grant income and the associated expenses are included in research and development expenses on the statement of operations and comprehensive loss. When grant proceeds are initially received, they are recorded as deferred income and restricted cash. Grant proceeds used to pay for study costs are expensed as incurred with a corresponding amount of grant income recognized through a reduction of the deferred income balance. The Company classifies the balance of cash received from grants as restricted cash when the proceeds from the grant have been designated for use in specified research. During the years ending December 31, 2025 and 2024, the Company recorded grant income of $81,095 and $463,811, respectively, from the "R&D Grant" described in Note 3.

Income Taxes – The Company uses the asset and liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on future tax consequences attributable to differences between the consolidated financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that include the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to the amount for which realization is more likely than not.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than a 50% likelihood of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest and penalties related to unrecognized tax benefits in income tax expense. To date, there have been no interest or penalties recorded in relation to unrecognized tax benefits.

Loss Per Share – Basic loss per share is computed by dividing net loss available to common stockholders by the weighted-average number of common stock outstanding during the reporting period. Diluted earnings per share includes the effect of potentially dilutive securities, including stock options, warrants, and convertible debentures, using the treasury stock method. Potentially dilutive securities are included in diluted earnings per share only to the extent they reduce earnings per share.

Fair Value Measurements – Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Assets and liabilities recorded at fair value are measured and classified in accordance with a three-tier fair value hierarchy based on the observability of the inputs available in the market used to measure fair value:

Level 1 – Observable inputs that reflect quoted prices for identical assets or liabilities in active markets.

Level 2 – Inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and credit ratings.

Level 3 – Financial instruments whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the instrument.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. To the extent that a fair value measurement is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3.

The Company's recurring fair value measurements include those related to warrant liabilities (see Note 9), bonus right liabilities (see Note 8), and CAD Option liabilities (see Note 9), all of which are considered to be Level 3 measurements due to the use of significant unobservable inputs, including expected volatility and expected term. These inputs are inherently uncertain and require significant judgment; accordingly, changes in these assumptions could have a material impact on the fair value measurement. In general, increases (decreases) in the expected volatility assumptions would result in higher (lower) fair value measurements, and increases (decreases) in the expected term assumptions would generally result in higher (lower) fair values.

The carrying amounts of cash and cash equivalents, restricted cash, accounts receivable, inventory, prepaid expenses and other current assets, accounts payable and accrued liabilities, and deferred income are considered to be representative of their respective fair values because of the short-term nature of these accounts.

Recent Adopted Accounting Pronoucements

In December 2023, the Financial Accounting Stand ("FASB") issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This update requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 2023-09, effective December 31, 2025, in these consolidated financial statements. ASU 2023-09 only impacted the disclosures and did not impact the consolidated financial statements. See Note 8, Income Taxes, for disclosures related to the adoption of ASU 2023-09.

New Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update No. 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses" ("ASU 2024-03"), which requires disaggregation of certain costs in a separate note to the financial statements, such as the amounts of employee compensation, depreciation and intangible asset amortization, included in each relevant expense caption in annual and interim consolidated financial statements. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027 on a retrospective or prospective basis, with early adoption permitted. The Company is evaluating the effect that ASU 2024-03 will have on its financial statement disclosures.

The Company considers the applicability and potential impact of all recently issued accounting pronouncements; those not specifically identified in this disclosure are either not applicable to the Company or not expected to have a material effect on our financial condition or results of operations.

NOTE 3 – INVENTORY

Inventory consists of the following at December 31:

	2025	2024
Raw materials	$ 3,725,336	$ -
Work in progress	725,460	615,133
Finished goods	672,700	-
Total	**$ 5,123,496**	**$ 615,133**

NOTE 4 – OTHER BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets consisted of the following at December 31:

	2025	2024
Prepaid insurance and other expenses	$ 2,123,379	$ 795,141
Prepaid FDA user fees	994,979	-
Prepaid legal expenses	1,465	23,396
Deferred offering costs	223,096	-
Others	202,532	253,426
Prepaid expenses and other current assets	**$ 3,545,451**	**$ 1,071,963**

Accounts payable and accrued expenses consisted of the following at December 31:

	2025	2024
Accounts payable	$ 3,067,616	$ 872,676
Accrued gross-to-net discounts	993,413	-
Accrued inventory costs	450,321	-
Accrued payroll and bonuses	2,872,403	643,063
Other accrued liabilities	1,593,151	923,550
Accounts payable and accrued liabilities	**$ 8,976,904**	**$ 2,439,289**

NOTE 5 – INTANGIBLE ASSETS

The Company's intangible assets consist entirely of license of intellectual property. Details related to the amounts of these licenses were as follows at December 31:

	2025	2024
Gross amount	$ 1,185,633	$ 1,185,633
Accumulated amortization	(794,210)	(772,664)
Intangible assets, net	**$ 391,423**	**$ 412,969**

The weighted-average remaining useful life of intangible assets was 18.17 years and 5.17 years at December 31, 2025 and 2024, respectively. Amortization expense for the years ended December 31, 2025 and 2024 was $21,546 and $79,875, respectively. During the year ended December 31, 2024, the Company reported an impairment loss of $39,166 related to one of its licenses.

The following table outlines the estimated future annual amortization expense related to intangible assets as of December 31, 2025:

Year Ending December 31,	
2026	$ 21,546
2027	21,546
2028	21,546
2029	21,546
2030	21,546
Thereafter	283,693
Total	**$ 391,423**

Change in Useful Life of Intangible Asset

The Company completed a review of the estimated useful life of its intangible asset after a patent application, related to the Memogain License, was granted in January 2025. The patent protection was extended to February 2044. Management determined that the estimated useful life of the license should be extended for an additional 14 years. Effective January 1, 2025, the Company extended the estimated remaining useful life of the license from 5 years to 19 years.

This change in estimate has been applied prospectively and, as a result of this change, amortization expense decreased by approximately $57,496 for the year ended December 31, 2025, compared to the prior amortization schedule.

NOTE 6 – PROMISSORY NOTE

In March 2015, the Company issued a promissory note of $1,400,000 to Neurodyn Life Sciences Inc ("NLS"), a related party through a common director, for the acquisition of the ALPHA-1062 Technology described in Note 16.

In March 2023, the Company and NLS agreed to an amendment to the promissory note pursuant to which the interest rate was increased from 2% to 5.5% and the maturity date was extended from December 31, 2022, to July 15, 2024, with interest-only payments due until maturity.

In April 2024, the Company and NLS agreed to another amendment to the promissory note pursuant to which the interest rate was increased from 5.5% to 7% and the maturity date was extended from July 15, 2024, to July 15, 2025. As required by the amendment, $300,000 of the outstanding principal balance was repaid prior to December 31, 2024, with the remaining principal balance due at maturity. During 2025, the remaining principal balance and accrued interest were repaid and the promissory note was no longer outstanding at December 31, 2025.

NOTE 7 – CONVERTIBLE DEBENTURES AND CONVERSION FEATURE LIABILITY

The following table summarizes the activity for the convertible debentures and conversion feature liability as of and for the years ended December 31, 2025 and 2024:

	Convertible Debentures	Conversion Feature Liability	Warrant Liabilities	Total
Balance, January 1, 2024	$ -	$ -	$ -	$ -
Proceeds	4,545,000	-	-	4,545,000
Allocation of proceeds to conversion feature liability	(3,359,716)	3,359,716	-	-
Allocation of proceeds to warrant liabilities	(1,185,284)	-	3,238,759	2,053,475
Accrued interest	65,996	-	-	65,996
Revaluation of conversion feature liability	-	2,076,421	-	2,076,421
Revaluation of warrant liabilities	-	-	(1,484,661)	(1,484,661)
Reallocation on conversion of convertible debentures	(65,996)	(5,436,137)	892,745	(4,609,388)
Balance, December 31, 2024	**-**	**-**	**2,646,843**	**2,646,843**
Revaluation of warrant liabilities	-	-	(227,387)	(227,387)
Balance, December 31, 2025	**$ -**	**$ -**	**$ 2,419,456**	**$ 2,419,456**

On September 24, 2024, the Company entered into Securities Purchase Agreements ("SPAs") with various third party lenders for the issuance of convertible debentures ("Debentures") and warrants to purchase 430,805 common shares of the Company at an exercise price of $10.55 per share until September 24, 2029 ("Initial Debenture Warrants") for $4,545,000. As described below, in November 2024 the Debentures automatically converted pursuant to their terms into 801,413 Common Shares.

Prior to their conversion, the Debentures accrued interest at 10% per annum and were due and payable on September 24, 2026 ("Maturity Date"). At any time prior to the Maturity Date, the holder had the option to convert their Debenture and any accrued interest into Common Shares at a price of $10.55 ("Conversion Price"). Upon the completion of a Qualified Offering, being an offering of the Company's securities for at least $10 million in aggregate gross proceeds in coordination with the simultaneous uplisting of Common Shares onto a United States national securities exchange, the Debentures would automatically convert into the securities, including warrants, on the same terms as were applicable in the Qualified Offering at the lower of (i) the Conversion Price or (ii) the per security offering price in the Qualified Offering. If, prior to the Maturity Date or the completion of a Qualified Offering, the last trading price of the Common Shares exceeded 250% of the Conversion Price for 10 consecutive trading days, the Debentures and accrued interest would have automatically converted into Common Shares at the Conversion Price.

Upon the closing of a Qualified Offering, holders of the Initial Debenture Warrants were entitled to receive an additional 50% of warrants ("Additional Debenture Warrants") with identical terms as the Initial Debenture Warrants. Refer to Note 9 for additional details related to the Initial and Additional Debenture Warrants.

On November 13, 2024, the Debentures automatically converted pursuant to their terms into 801,413 Common Shares at a conversion price of $5.75, this being the public offering price per share in the Company's United States initial public offering. Also on this date, the Company issued the Additional Debenture Warrants exercisable into 215,421 Common Shares at an exercise price of $7.19 per share. In addition, the exercise price of the Initial Debenture Warrants was adjusted from $10.55 per share to $7.19 per share.

The Company determined that the conversion features embedded in the Debentures met the definition of a derivative that was required to be bifurcated from the Debentures. As a result, the Company recognized the embedded derivative as a conversion feature liability and recorded a corresponding debt discount related to the Debentures that was accreted to interest over the period the Debentures were outstanding. The conversion feature liability was initially measured at fair value and subsequently remeasured to fair value at the end of each reporting period, with any changes in fair value reported as a gain or loss on the consolidated statement of operations and comprehensive loss. During the year ended December 31, 2024, the Company recognized a loss on the revaluation of the conversion feature liability of $2,076,421. Additionally, the Company recognized debt issuance costs relating to the convertible features and warrants of $459,360 during the year ended December 31, 2024.

The initial fair value of the conversion feature liability was determined to be $6,598,475 using the Monte Carlo simulation model with the following assumptions:

Risk-free interest rate	3.51%
Dividend yield	–%
Volatility	88%
Probability of automatic conversion under qualified offering	70%
Expected life	5 years

NOTE 8 – OTHER LONG-TERM LIABILITIES

The Company adopted a bonus policy pursuant to which it may grant bonus rights payable in cash to certain eligible participants, including employees, officers, or consultants of the Company. These bonus rights are subject to certain vesting provisions and are remeasured each reporting date with the change in fair value recognized in selling, general and administrative expense in the consolidated statements of operations and comprehensive loss.

During 2022, certain executives of the Company were granted the ability to earn up to 370,448 bonus rights entitling them to a cash bonus equal to an amount by which the fair market value of one common stock (calculated as the 30-day Volume Weighted Average Price ("VWAP") per common share) exceeds $39.50 multiplied by the number of bonus rights vested. The bonus rights will be earned in tranches based on the price of the Company's common share exceeding certain thresholds. Initially, the earned bonus rights would vest and be payable on the earlier of a date of a change of control or April 15, 2024.

On April 16, 2024, the Company amended the vesting date of the bonus rights agreements to the earlier of April 28, 2027, the date of a change of control, or the date of the attainment of the business value threshold with respect to any tranche. Additionally, the grant price was reduced from $39.50 to $29.75. As of December 31, 2025 and 2024, a total of 95,071 bonus rights had been vested.

At December 31, 2025 and 2024, the Company recognized a bonus right liability of $47,181 and $102,783, respectively. Total compensation expense (recovery) for the bonus rights recognized within selling, general and administrative expenses for the years ended December 31, 2025 and 2024 was $(54,113) and $16,160, respectively. Total compensation expense (recovery) for the bonus rights recognized within research and development expenses for the years ended December 31, 2025, and 2024, was $(1,489) and $2,498, respectively. As of December 31, 2025, and 2024, there was $28,791 and $264,043, respectively, of unrecognized compensation expense related to the bonus right awards.

The bonus right awards are considered liability-based awards and are remeasured to fair value at each reporting date and on settlement date. The following weighted average assumptions were used in the Black-Scholes option-pricing model for the valuation of the bonus rights liability as of December 31:

	2025	2024
Risk-free interest rate	3.48%	4.25%
Expected life (in years)	1.33	2.33
Volatility	79.84%	166.95%
Weighted average fair value per bonus right	$ 0.19	$ 3.30

As of December 31, 2025, and 2024, 98,021 and 111,052 bonus right awards, respectively, were expected to vest.

NOTE 9 – STOCKHOLDERS' EQUITY

Authorized Share Capital

The Company is authorized to issue the following share capital:

- Unlimited common voting shares without par value ("Common Stock")
- Unlimited Class A restricted voting shares without par value ("Restricted Stock")
- Unlimited Class B Preferred Series A voting shares without par value, convertible on a 1:1 basis into Common Share ("Class B Preferred Stock")

At the Market Offering

On August 22, 2025, the Company entered into an At the Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") as sales agent. Under the terms of the ATM Agreement, the Company will be entitled to sell, at its sole discretion and from time to time as it may choose, common stock in the capital of the Company ("Stock") through Wainwright, with such sales having an aggregate gross sales value of up to $75.0 million (the "Offering"). The ATM Agreement will remain in full force and effect until the date that the ATM Agreement is terminated in accordance with the terms therein.

Subject to the terms and conditions of the Agreement, Wainwright will use its commercially reasonable efforts to sell the Stock from time to time, based upon the Company's instructions. However, the Company has no obligation to sell any of the Stock, and may at any time suspend offers under the Agreement or terminate the Agreement. The Company has provided Wainwright with customary indemnification rights, and Wainwright will be entitled to a commission at a commission rate of up to 3.0% of the gross sales price of the Stock sold.

Through December 31, 2025, the Company has not issued Common Stock under the ATM Agreement.

Public Offering

On October 2, 2025, the Company completed a public offering of Common Stock by issuing 4,651,516 shares of Common Stock at a public offering price of $6.25 per share and 948,484 pre-funded warrants exercisable to Common Stock with an exercise price of $0.001 per share for total gross proceeds to the Company of $35 million. In connection with the issuance of the Common Stock for this offering, the Company incurred underwriting fees of $2,110,875 and legal and other advisory fees $95,096.

On October 17, 2025, the underwriter of the Company's public offering exercised its over-allotment option in full to purchase an additional 840,000 shares of Common Stock at the public offering price of $6.25 per share for additional gross proceeds of $5.25 million. In connection with this issuance, the Company incurred $341,250 in underwriter fees.

The pre-funded warrants have an exercise price of $0.001 per common stock, subject to proportional adjustments in the event of share dividends and splits, pro rata distributions, subsequent rights offerings and similar events. The pre-funded warrants are exercisable at any time after their original issuance, subject to certain beneficial ownership limitations, and only terminate upon exercise.

Initial Public Offering in the United States

On November 13, 2024, the Company completed a public offering in the United States by issuing 8,695,653 Common Stock at an offering price of $5.75 per share for gross proceeds of $50,000,005. In connection with this offering, the Company incurred underwriting fees of $3,826,624, legal and other advisory fees of $1,374,814, and listing fees of $133,633. In addition, the Company issued warrants exercisable into 608,696 Common Stock (the "IPO Agent Warrants") with an estimated fair value of $2,381,051.

On December 12, 2024, the underwriter of the Company's public offering in the United States partially exercised its over-allotment option to purchase an additional 488,506 common shares at the public offering price of $5.75 per share for additional gross proceeds of $2,808,910.

Shares Issued for Services

In May 2023, the Company entered into a three-year consulting services agreement (the "Spartan Consulting Agreement") with Spartan Capital Securities, LLC ("Spartan") under which Spartan will provide advising and assisting on potential business development transactions, strategic introductions, assisting management with enhancing corporate and stockholder value, and capital raising advice. In January 2024, the Company paid a consulting fee of $320,000 and issued 582,331 Common Stock valued at $3,202,823 to Spartan and its assignees pursuant to the Spartan Consulting Agreement, of which $928,874 was recognized as share issuance costs and $2,273,949 was recognized as selling, general and administrative expenses.

Unit Offering

In January 2024, the Company completed an offering of 678,630 units at a price of $5.50 for total gross proceeds of $3,732,469 (the "2024 Unit Offering"). Each unit consisted of one Common Stock and one warrant with each warrant entitling the holder to purchase an additional Common Stock of the Company at the initial pricing of $7.75 per share until January 2027 (the "2024 Unit Offering Investor Warrants"). In connection with the closing of 2024 Unit Offering, the Company paid cash commissions of $391,178, incurred legal fees of $14,575, and issued a warrants exercisable into 41,493 Common Shares (the "Unit Offering Agent Warrants") with an estimated fair value of $582,245. Each Unit Agent Warrant is exercisable into one Common Share of the Company at an exercise price of $7.75 and expires in January 2027. Collectively, the 2024 Unit Offering Investor Warrants and the Unit Offering Agent Warrants are referred to hereafter as the "2024 Unit Offering Warrants").

Summary of Outstanding Warrants

The following table summarizes warrant activity during the years ended December 31, 2025 and 2024:

	Number of Warrants	Weighted Average Exercise Price
Balance, January 1, 2024	**1,749,192**	**$ 7.66**
Issued	2,009,241	7.39
Exercised	(30,000)	10.00
Expired	(92,471)	10.00
Balance, December 31, 2024	**3,635,962**	**$ 7.37**
Issued	948,484	0.00
Exercised	(141,000)	7.23
Balance, December 31, 2025	**4,443,446**	**$ 5.84**

A summary of all warrants outstanding and exercisable as of December 31, 2025 is as follows:

Warrants	Shares Exercisable	Exercise Price	Expiry Date
Equity-classified warrants:			
Private placements	2,232,412	$7.08 – 7.75	August 2026 to March 2028
Prefunded warrants	948,484	$ 0.001	N/A
Liability-classified warrants:			
CAD Warrants	86,200	$7.11 (CAD$9.75)	February 16, 2028
CAD Warrants	15,810	$7.11 (CAD$9.75)	March 15, 2028
Initial Debenture Warrants	430,805	$ 7.19	September 24, 2029
Additional Debenture Warrants	215,421	$ 7.19	November 13, 2029
IPO Agent Warrants	514,314	$ 7.18	November 8, 2029
	4,443,446		

CAD Warrants Liability

On August 31, 2023, the Company's functional currency changed to the USD from the CAD; as such, the Company recorded a derivative liability on the warrants outstanding with CAD exercises prices (the "CAD Warrants"). This derivative liability is being remeasured to fair value at each reporting period and on settlement date.

As of December 31, 2025, and December 31, 2024, the fair value of the CAD Warrants derivative liability was $326,198 and $503,129, respectively. During the years ended December 31, 2025, and December 31, 2024, the Company recorded a $176,931 gain and a $340,179 loss, respectively, from the change in the fair value of the CAD Warrants.

The following weighted average assumptions were used in the Black-Scholes option-pricing model to remeasure the fair value of the CAD Warrants at December 31:

	2025	2024
Market price of public stock	$ 6.50	$ 5.89
Risk-free interest rate	3.51%	4.27%
Dividend yield	-	-
Expected life (in years)	2.14	3.14
Volatility	91%	158%
Weighted average fair value per warrant	$ 3.20	$ 4.93

Debentures Warrants Liability

In connection with transactions described in Note 8 related to the Convertible Debentures, the Company issued Initial Debenture Warrants and Additional Debenture Warrants during 2024. The Initial Debenture Warrants were exercisable at a price of $10.55 per share until September 24, 2029. However, the exercise price of the Initial Debenture Warrants were subject to adjustment upon the completion of a Qualified Offering to the lower of (i) the existing Debenture Warrant exercise price, (ii) the exercise price of any common share purchase warrants issued in the Qualified Offering, or (iii) if no common share purchase warrants are issued in the Qualified Offering, the closing price of the common shares on the Canadian Securities Exchange (as converted into U.S. dollars) immediately prior to the pricing news release of the Qualified Offering. As a result of the Company's November 2024 initial public offering in the United States, the exercise price of the Initial Debenture Warrants was adjusted to $7.19 per share.

The fundamental transaction clause in the underlying warrant agreements stipulates that the expected volatility is determined as the greater of 100% and the 30-day volatility, as calculated from the HVT function on Bloomberg. Because the volatility input is predetermined and fixed in the warrant agreements as "an expected volatility equal to the greater of 100% and the 30-day volatility from the "HVT" function on Bloomberg", the Initial and Additional Debenture Warrants are not considered to be indexed to the Company's stock and, as a result, fail the "fixed-for-fixed" condition (i.e., both the exercise price and the number of shares to be issued are not "fixed" at issuance). Instead, the Initial and Additional Debenture Warrants are classified as liabilities that are remeasured to fair value each reporting period.

At December 31, 2025 and 2024, the fair value of the Initial and Additional Debenture Warrants liabilities totaled $2,419,456 and $2,646,843, respectively. During the years ended December 31, 2025 and 2024, the Company recognized a gain of $227,387 and a loss of $1,481,661, respectively, from the change in fair value of the Initial and Additional Debenture Warrants liabilities.

The following weighted average assumptions were used in a binomial lattice model to remeasure the fair value of the Initial and Additional Debenture Warrants as of December 31:

	2025	2024
Market price of public stock	$ 6.50	$ 5.89
Risk-free interest rate	3.56%	4.38%
Dividend yield	-	-
Expected life (in years)	3.78	4.73
Volatility	87%	94%
Weighted average fair value per warrant	$ 3.74	$ 4.10

IPO Agent Warrants

Upon completion of its November 2024 initial public offering, the Company issued 608,696 IPO Agent Warrants and an additional 34,196 IPO Agent Warrants for the over-allotment. Each IPO Agent Warrant is exercisable into one Common Share of the Company at an exercise price of $7.18 per share and has a term of five years.

The terms of the IPO Agent Warrants include a fundamental transaction clause that stipulates that the expected volatility is determined as the greater of 100% and the 30-day volatility, as calculated from the HVT function on Bloomberg. Because the volatility input is predetermined and fixed in the warrant agreements as "an expected volatility equal to the greater of 100% and the 30-day volatility from the "HVT" function on Bloomberg", the IPO Agent Warrants are not considered to be indexed to the Company's stock and, as a result, fail the "fixed-for-fixed" condition (i.e., both the exercise price and the number of shares to be issued are not "fixed" at issuance). Instead, the IPO Agent Warrants are classified as liabilities that are remeasured to fair value each reporting period.

During the year ended December 31, 2025, 128,578 IPO Agent Warrants were exercised, which resulted in $903,245 of the warrant liability being reclassified to share capital. At December 31, 2025 at 2024, the estimated fair value of outstanding IPO Agent Warrants was $2,044,681 and $2,670,386, respectively. During the years ended December 31, 2025 and 2024, the Company recognized a loss of $277,540 and a loss of $179,293, respectively, from the change in fair value of the IPO Agent Warrants liability.

The following weighted average assumptions were used in the Black-Scholes option-pricing model for the revaluations of the IPO Agent Warrants as of December 31:

	2025	2024
Market price of public stock	$ 6.50	$ 5.89
Risk-free interest rate	3.64%	4.38%
Dividend yield	-	-
Expected life (in years)	3.86	4.86
Volatility	86%	95%
Weighted average fair value per warrant	$ 3.97	$ 4.15

Equity Incentive Plans

The Company's 2025 Stock and Incentive Plan (the "2025 Incentive Plan") for its employees, officers, consultants, advisors and non-employee Directors was approved by the stockholders on June 19, 2025. The objective of the 2025 Incentive Plan is to provide equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents, or other stock-based awards. The 2025 Incentive Plan authorizes grants of stock awards covering up to 2,000,000 Common Shares. All stock options are granted with an exercise price equal to the stock's estimated fair market value at the date of grant, and generally have contractual terms of ten years and vest over three years. At December 31, 2025, 1,946,800 Common Shares were available for issuance under the 2025 Incentive Plan.

The Company's 2023 Share Option Plan (the "2023 Option Plan") for its officers, directors, employees and consultants was approved by stockholders on June 27, 2023. Pursuant to the 2023 Option Plan, the Company may grant non-transferable share options totaling in aggregate up to 20% of the Company's issued and outstanding Common Shares and Restricted Shares, exercisable for a period of up to ten years from the date of grant, and at an exercise price that will not be lower than the greater of the last closing price for the Common Shares as quoted on the CSE: (i) on the trading day prior to the date of grant; and (ii) the date of grant. All options granted pursuant to the 2023 Option Plan will be subject to such vesting requirements as may be imposed by the Board. In the event of a Change of Control, as defined in the 2023 Option Plan, all unvested options will vest immediately. No additional shares can be granted under this plan.

The 2022 Option Plan was previously adopted by the board and approved by stockholders on July 19, 2022, pursuant to which incentive share options were granted to certain directors, officers, employees and consultants (the "2022 Option Plan"). Under the 2022 Option Plan, the Company could grant non-transferable share options totaling in aggregate up to 10% of the Company's issued and outstanding Common Shares, exercisable for a period of up to ten years from the date of grant, and at an exercise price which is not less than that permitted by the TSX-V. In connection with listing of the Common Shares on the CSE, the Company adopted the 2023 Option Plan and determined that the 2022 Option Plan be closed to new grants. The options outstanding under the 2022 Option Plan, issued prior to the adoption of the 2023 Option Plan ("2022 Options") are not included in the maximum number of share options available for grant pursuant to the 2023 Option Plan and are not subject to the terms of the 2023 Option Plan; as such, the 2022 Options will continue to be governed by the 2022 Option Plan. No additional shares can be granted under this plan.

Stock Options

Equity-Classified Awards with Service-Based Vesting

The following table summarizes activity for equity-classified common stock options with service-based vesting conditions:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value[(1)]
Balance, December 31, 2024	**37,132**	**$ 5.45**	**9.57**	**$ 29,240**
Granted	1,266,297	5.76		
Exercised	(134)	0.01		127
Cancelled	(43,335)	5.80		
Balance, December 31, 2025	**1,259,960**	**$ 5.93**	**9.12**	**$ 817,366**
Options exercisable, December 31, 2025	**455,629**	**$ 5.90**	**8.96**	**$ 285,852**

(1) The aggregate intrinsic values were calculated as the difference between the exercise price of the options and the closing price of the Company's Common Shares. The calculation excludes options with an exercise price higher than the closing price of the Company's share on the reporting date.

The following weighted average assumptions were used in the Black-Scholes option-pricing model for the valuation of equity-classified Common Share options issued during the years ended December 31:

	2025	2024
Risk-free interest rate	4.16%	4.59%
Expected life (in years)	5.77	10
Volatility	95%	82%
Weighted average grant-date fair value per option	$ 4.51	$ 4.27

The following table summarizes the allocation of share-based compensation expense related equity-classified to awards with service conditions during the years ended December 31:

	2025	2024
Research and development	$ 101,756	$ -
Selling, general and administrative [(1)]	3,671,047	-
Total share-based compensation	**$ 3,772,803**	**$ -**

(1) Stock-based compensation expense for the year ended December 31, 2025 included $34,593 of incremental stock-based compensation on the consolidated statement of operations and comprehensive loss. This expense related to the modification of 9,691 vested stock options held by one individual to extend the post-termination exercise period from 90 days following the individual's last day of service as a member of the Company's board of directors to two years from that date. The fair value of the options immediately before and after the modification was estimated using Black-Scholes option-pricing model.

Total share-based compensation cost not yet recognized related to equity-classified unvested stock options was $1,941,171 at December 31, 2025 and is expected to be recognized over a weighted-average period of 2.17 years. The total fair value of options that vested during the years ended December 31, 2025 and 2024 was $5.90 and $10.00, respectively.

Liability-Classified CAD Options

The following table summarizes activity for liability-classified CAD Options with service-based vesting conditions:

	Number of Options	Weighted Average Exercise Price (in USD)	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value[(1)]
Balance, December 31, 2024	**851,467**	**$ 4.54**	**8.30**	**$ 1,175,887**
Granted	-	-		
Exercised	(89,667)	4.330		343,278
Cancelled	(3,500)	4.01		
Balance, December 31, 2025	**758,300**	**$ 4.77**	**7.12**	**$ 1,456,902**
Options exercisable, December 31, 2025	**680,844**	**$ 4.47**	**6.92**	**$ 1,427,630**

(1) The aggregate intrinsic values were calculated as the difference between the exercise price of the options and the closing price of the Company's Common Stock. The calculation excludes options with an exercise price higher than the closing price of the Company's stock on the reporting date.

The following weighted average assumptions were used in the Black-Scholes option-pricing model to remeasure the fair value of liability-classified CAD Options as of the years ended December 31:

	2025	2024
Risk-free interest rate	3.52%	4.20%
Expected life (in years)	3.30	3.27
Volatility	90.26%	72.39%
Weighted average fair value per option	$ 4.39	$ 3.47

The following table summarizes the allocation of share-based compensation expense related liability-classified CAD options during the years ended December 31:

	2025	2024
Research and development	$ 28,473	$ 2,756
Selling, general and administrative [(1)]	1,121,249	297,170
Total share-based compensation	**$ 1,149,722**	**$ 299,926**

Total share-based compensation cost not yet recognized related to liability-classified unvested stock options was $152,891 at December 31, 2025 and is expected to be recognized over a weighted-average period of 1.9 years.

The following table presents the changes in the CAD Options liability for the years ended December 31, 2025 and 2024:

Fair value on date of November 2024 US initial public offering	$ 2,068,292
Share-based compensation expense for 2024	299,926
Fair value of CAD Option liability at December 31, 2024	2,368,218
Fair value of exercised awards	(343,278)
Share-based compensation expense for 2025	1,149,722
Fair value of CAD Option liability at December 31, 2025	**$ 3,174,662**

ACI Canada Legacy Performance Options

The Company retained ACI Canada's share option plan whereby ACI Canada could grant share options to directors, officers, employees and consultants enabling them to acquire common shares. Options granted had a maximum term of ten years and the board of directors determined the vesting requirements. From time to time, the Company granted performance-based share options to management and consultants. These options vest based on the Company's achievement of certain performance goals and operational metrics, as applicable, subject to continuous employment by each recipient.

The following table summarizes ACI Canada legacy performance option activity for the Company:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value[(1)]
Balance, December 31, 2024	**265,642**	**0.22**	**3.48**	**$ 1,506,321**
Balance, December 31, 2025	**265,642**	**0.22**	**2.48**	**1,668,363**
Options exercisable, December 31, 2025	**258,362**	**$ 0.22**	**2.46**	**$ 1,622,863**

(1) The aggregate intrinsic values were calculated as the difference between the exercise price of the options and the closing price of the Company's common share. The calculation excludes options with an exercise price higher than the closing price of the Company's shares on the reporting date.

The following table summarizes the total amount of share-based compensation expense related to performance conditions for ACI Canada legacy performance options during the years ended December 31:

	2025	2024
Research and development	$ -	$ 118,514
Total share-based compensation	**$ -**	**$ 118,514**

As of December 31, 2025, there was no unrecognized share-based compensation expense relating to service condition awards.

NOTE 10 – CMSI LICENSE AND COLLABORATION AGREEMENT

On January 8, 2025 (the "Effective Date"), the Company entered into a License, Collaboration and Distribution Agreement (the "CMSI License Agreement") with CMSI International Development and Management Limited ("CMSI"), pursuant to which the Company granted CMSI an exclusive, transferable, sub-licensable, and royalty-bearing license to develop, register, manufacture, import, export, and commercialize ZUNVEYL (the "Product") in the Asia-Pacific region (excluding Japan), Australia, and New Zealand (the "Territory"). ZUNVEYL is a next generation acetylcholinesterase inhibitor approved in the US for the treatment of mild-to-moderate Alzheimer's disease.

Under the terms of the CMSI License Agreement, the Company received a one-time, non-refundable, non-creditable upfront payment of $3.0 million in January 2025 and is eligible to receive up to $11.0 million in development and regulatory milestone payments, as well as up to $30.0 million in sales milestone payments. In addition, CMSI is obligated to pay annual royalties of 9% on net sales within the defined royalty term.

The CMSI License Agreement remains in effect for an initial term of 20 years from the Effective Date and will automatically renew for additional five-year terms unless either party provides notice of non-renewal at least six months prior to the expiration of the then-current term.

The total transaction price at inception was determined to consist of the $3.0 million upfront payment. The Company identified two distinct performance obligations: (1) the license to the Company's pharmaceutical intellectual property, and (2) certain regulatory, technical, and clinical assistance to be provided by the Company and the Joint Steering Committee, which includes representatives from both the Company and CMSI, through the expected commercialization of the Product.

The upfront payment of $3 million was allocated to the identified performance obligations based on their relative standalone selling prices (SSPs). The SSP for the license was determined using an adjusted market assessment approach, under which the Company applied its estimate of a market participant's rate of return on similar licensing arrangements to calculate the present value of the net cash flows that may be received from CMSI. In estimating the net cash flows that may be received from CMSI, the Company considered both the likelihood and expected timing of future payments from development milestones, sales milestones, and royalties. The SSP for services was based on estimated costs plus the Company's estimate of a reasonable profit margin for similar services

License of Intellectual Property

The license to the Company's intellectual property represents a distinct performance obligation. The license was transferred to CMSI on the Effective Date to satisfy this performance obligation. The Company allocated $2,396,600 of the total transaction price to the license and recognized the corresponding revenue in 2025.

Regulatory, Technical, and Clinical Assistance

The Company's promise to provide supporting services, whether directly or in participation with the Joint Steering Committee, to CMSI is expected to be primarily fulfilled during the early stages of the contract through commercialization of the Product. These services represent a distinct performance obligation and the $603,400 of transaction price allocated to these services is being recognized over time on a percentage of completion basis, using a measure of progress that compares the Company's actual efforts expended to-date to its total estimated efforts. As of December 31, 2025, the Company had recognized $433,221 of revenue related to these services. The remaining $170,179 of transaction price allocated to this performance obligation is included in deferred revenue at December 31, 2025 and is expected to be fully recognized by December 31, 2027.

Development and Regulatory Milestone Payments

The potential development and regulatory milestone payments are contingent upon the occurrence of certain milestones as defined in the CMSI License Agreement. These payments have been fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. As such, they have been excluded from the transaction price. In future reporting periods, the Company will re-evaluate the probability of achievement of each milestone and any related constraint and, if necessary, adjust its estimate of the overall transaction price. As of December 31, 2025, the Company has not recognized any revenue associated with the development and regulatory milestones.

Sales Milestone Payments and Royalties

Any consideration related to sales milestones or royalties will be recognized if and when the related sales occur as such amounts are determined to relate predominantly to the license granted to CMSI. Accordingly, this consideration has been excluded from the transaction price. No allocation to performance obligations will be performed, as both the license and related assistance are expected to be satisfied by the time sales milestones and royalties are earned. No sales milestone or royalty revenue was recognized as of December 31, 2025.

Pass Through Costs

Included within licensing revenue is revenue from the sale of active pharmaceutical ingredient ("API") and finished goods to CMSI in connection with the CMSI License Agreement. These API and finished goods sales support CMSI's development and regulatory activities and are priced at cost plus a margin. The Company also includes certain pass through reimbursable costs within these revenue totals. These amounts are recognized on a gross basis. Revenue related to API sales and reimbursable costs is recognized upon API shipment or delivery, depending on the applicable shipping terms. During the year ended December 31, 2025, the Company recognized $598,430 in licensing revenue relating to the pass through costs.

As of December 31, 2025, $561,293 was due from CMSI for the CMSI License Agreement.

NOTE 11 – R&D GRANT

On June 5, 2023, the Company was awarded a $750,000 research and development grant from the Army Medical Research and Material Command for a pre-clinical study on the use of the ALPHA-1062 Intranasal to reduce blast mTBI (mild Traumatic Brain Injury) induced functional deficit and brain abnormalities ("R&D Grant"). The R&D Grant is issued in collaboration with the Seattle Institute of Biomedical and Clinical Research and endorsed by the Department of Defense. Funds received from the R&D grant are restricted and to be used solely as outlined in the grant. The R&D grant funding will expire for use on September 30, 2028.

Per the R&D Grant, budget expenses are expected to include cost to carry out the clinical trials including personnel costs, materials and supplies, animal housing, publications, and travel costs. The Company classifies any cash received from the R&D Grant that has not yet been used to pay ongoing R&D grant expenditures as restricted cash, as the proceeds from the grant are to be designated for the specified grant research.

Activity related to the R&D grant was as follows for the years ended December 31:

	2025	2024
Cash received	$ 174,675	$ 373,825
Grant income recognized	$ 81,095	$ 463,881
Grant expenses recognized	$ 81,095	$ 463,881

NOTE 12 – FOREIGN CURRENCY CONTRACTS

The Company has an obligation to make periodic royalty payments from its sale of products incorporating technology that has been licensed from Neurodyn Life Sciences Inc. ("NLS"). Because these payments will be made in EUR the Company is exposed to cash flow variability resulting from changes in USD/EUR exchange rates. Therefore, during September 2025, the Company entered into several foreign currency forward and foreign currency collar contracts that are intended to hedge its exposure to changes in the USD/EUR exchange rates on or about the dates certain of the Company's forecasted royalty payments will be made.

The foreign currency forward and collar contracts are derivative instruments that must be accounted for at fair value. Each reporting period, the change in the fair value of each contract is recognized as a gain or loss classified as a component of Other income (expense) within the Company's consolidated statements of operations.

At December 31, 2025 foreign currency forward contracts to purchase EUR 341,051 remained outstanding. These contracts will settle at various dates between May 2026 and August 2026. The fair value of the foreign currency forward contracts was immaterial at December 31, 2025.

At December 31, 2025 foreign currency collar contracts with a notional amount of EUR 3,458,251 remained outstanding. These contracts will settle at various dates between March 2026 and November 2027. The fair value of the foreign currency collar contracts was immaterial at December 31, 2025.

NOTE 13 – INCOME TAXES

During 2025, the Company adopted ASU 2023-09 – Income Taxes (Topic 740): Improvements to income tax disclosures prospectively, and the associated disclosure changes have been reflected below.

Information on a domestic and foreign basis prior to and after adoption of ASU 2023-09:

	2025	2024
Income (loss) before income tax		
Canada	(11,324,919)	(14,166,830)
US	(9,344,957)	(621,897)
Total loss before income tax	(20,669,875)	(14,788,727)

The Company's consolidated effective income tax rate differs from the Canadian, or domestic, statutory federal tax rate. The effective tax rate is affected by recurring items in provincial, U.S. federal, state and other foreign jurisdictions, such as tax rates and the proportion of income earned in those jurisdictions. The effective tax rate is also affected by other items such as the impact of transactions that are taxable or deductible at lower inclusion rates, changes in net unrecognized tax benefits, changes in income tax laws, and other items.

Income tax expense and effective tax rate reconciliation after adoption of ASU 2023-09:

	Year Ended December 31, 2025	
	Amount	Rate
Loss before income tax	$ (20,669,875)	
Income tax benefit at Canadian statutory federal tax rate [1]	(3,100,481)	15.0%
Income tax expense (benefit) resulting from:		
Canadian federal reconciling items:		
Non-deductible stock-based payments	725,275	(3.5)%
Change in valuation allowance	973,463	(4.7)%
Canadian provincial income taxes, net of federal effect [2], [3]	(1,358,990)	6.6%
Canadian provincial non-deductible stock-based payments	580,220	(2.8)%
Canadian provincial change in valuation allowance	778,770	(3.8)%
Foreign tax affects – U.S. federal reconciling items:		
U.S. federal tax rate differential	(560,697)	2.7%
Research and development tax credits	(64,000)	0.3%
Change in valuation allowance	2,016,856	(9.8)%
Other	9,584	0.0%
Income tax expense / effective tax rate	$ -	0.0%

(1) The Canadian federal statutory income tax rate of 15% is utilized in the reconciliation above as the company is incorporated in Canada and is comprised of basic Canadian federal tax rate of 38%, less federal abatement (10%) and general rate reduction (13%).
(2) The provincial jurisdiction that comprises the tax effect is the province of British Columbia.
(3) Includes the income tax affect amount for the related subnational jurisdiction such as tax rate differentials, nontaxable or nondeductible items, tax law changes, and other reconciling items.

Income tax expense and effective tax rate reconciliation before adoption of ASU 2023-09:

	Year Ended December 31, 2024
Federal statutory income tax	15.0%
Provincial and foreign subsidiary tax adjustment	11.7%
Permanent Differences	(9.2)%
Research and development credits	(6.7)%
Change in Valuation Allowance	(28.7)%
Other	17.9%
	0.0%

The significant components of the Company's deferred tax assets and liabilities are as follows at December 31:

	2025	2024
Deferred tax assets:		
Non-operating losses carry forwards	$ 17,846,000	$ 13,491,000
Tax credits carry forwards	333,000	396,000
Intangible assets	195,000	189,000
Research and development expenses capitalized	3,000	650,000
Stock issuance costs	1,517,000	1,476,000
Total deferred tax assets	$ 19,894,000	$ 16,202,000
Valuation allowance	(19,891,000)	(16,201,000)
Net deferred tax assets	3,000	1,000
Deferred tax liability		
Property and equipment	(3,000)	(1,000)
Total deferred tax liability	(3,000)	(1,000)
Net deferred income tax	**$ -**	**$ -**

There is no provision for income taxes because the Company has historically incurred operating losses and maintains a full valuation allowance. On an annual basis, the Company assesses the need to establish a valuation allowance for its deferred income tax assets, and if it is deemed more likely than not that its deferred income tax assets will not be realized, a valuation allowance is recorded. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income, of the necessary character, during the periods in which those temporary differences become deductible. Management considers the available carryback and carryforward periods, and projected future taxable income in making this assessment. Given the uncertainty of the amount and timing of future taxable income, if any, a valuation allowance has been recorded against the Company's deferred tax assets because, in the judgement of management, these are not more likely than not to be realized.

At December 31, 2025, the Company had, for Canadian tax purposes, non-capital losses aggregating approximately $57 million. These losses are available to reduce taxable income earned by ACI and ACI Canada in future years and expire between 2035 and 2045. As of December 31, 2025, the Company had federal net operating loss carryforwards, or NOLs, available of $11 million before consideration of limitations under Section 382 of the Internal Revenue Code of 1986, or Section 382 of the Code, as further described below. The NOL will carryforward indefinitely and be available to offset up to 80% of future taxable income each year.

Utilization of the Company's NOL and research and development credit carryforwards may be subject to substantial annual limitations in the event a cumulative ownership change has occurred, or that occur in the future, as required by Section 382 of the Code. An ownership change, as defined by the Code, occurs when certain stockholders or public groups acquire more than 50% of a company's outstanding common stock through a single transaction or series of transactions spanning a three-year period. Such an ownership change may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed such an ownership change analysis pursuant to Section 382 of the Code. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company accounts for uncertainty in income taxes in accordance with ASC 740, Income Taxes. Under this guidance, the Company recognizes the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination by the relevant taxing authorities.

The Company has evaluated its tax positions and concluded that there are no uncertain tax positions that require recognition or disclosure in the accompanying financial statements. Accordingly, no liability for unrecognized tax benefits has been recorded.

The Company's policy is to recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2025, the Company has not recorded any amounts for interest or penalties.

The Company is subject to income taxes in the United States, federal and various state jurisdictions. We are also subject to taxation in Canada . The Company is subject to income tax examinations by taxing authorities for all fiscal years..

The Company does not anticipate that the total amount of unrecognized tax benefits will materially change within the next 12 months.

NOTE 14 – NET LOSS PER SHARE

Net loss per common stock has been computed on the basis of the weighted-average number of common stock outstanding during the years ended December 31, 2025, and 2024. Diluted loss per share is computed similarly to basic loss per share, except that it includes the potential dilution that could occur if dilutive securities were exercised. We apply the treasury stock method in the calculation of diluted loss per share.

In years that liability-classified warrants and options are in the money, the Company determines whether such instruments are dilutive by calculating the effect on loss per share after considering both (a) the adjustment to the numerator that would result from reversing the impact of the change in fair value recorded to net loss during the period and (b) the adjustment to the denominator that would result from the incremental shares outstanding, using the treasury stock method, in an assumed exercise of these instruments at the beginning of the year.

The following table reconciles net loss and the weighted average shares outstanding for the basic calculation to the net loss and the weighted average shares outstanding for the diluted calculation for the years ended December 31:

	2025	2024
Numerator, diluted:		
Net loss	$ (20,669,875)	$ (14,788,727)
Adjustment for gain in fair value of warrant liabilities	(176,931)	-
Adjusted numerator, diluted	$ (20,846,806)	$ (14,788,727)
Denominator, diluted:		
Weighted average common stock outstanding	17,680,597	7,247,864
Dilutive effect of common stock warrants	832	-
Weighted average dilutive common stock	17,681,429	7,247,864
Net loss per share, diluted	$ (1.18)	$ (2.04)

The following potentially dilutive common shares related to outstanding securities for the years ended December 31, 2025 and 2024 were excluded from the computation of diluted net loss per share because their effect would have been anti-dilutive for the year:

	2025	2024
Warrants	3,392,952	2,777,647
Common Stock options	2,018,260	815,974
ACI Canada legacy performance options	265,642	265,642
Convertible debentures	-	430,805
Total anti-dilutive features	5,676,854	4,290,068

NOTE 15 – RELATED PARTY TRANSACTIONS AND BALANCES

Related Party Note Receivable

Prior to January 1, 2024, the Company advanced $55,000 to Alpha Seven Therapeutics, Inc. ("Alpha Seven") and accrued interest of $4,195. Alpha Seven is a related party through a common director and officers of the Company. During the year ended December 31, 2024, management determined the credit risk of the loan to Alpha Seven had increased significantly since initial recognition and the Company recorded a provision for credit losses for the outstanding principal balance of $55,000 and reversed all previously accrued interest. At December 31, 2025 and 2024, the amount of recognized principal and interest, net of reserves for credit losses, was $0.

NOTE 16 – COMMITMENTS AND CONTINGENCIES

ALPHA-1062 Technology

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

- The Company assumed all of NLS's obligations under the Memogain Asset Purchase Agreement which consisted of cumulative total payments to Galantos Pharma GmbH ("Galantos") of $11,739,000 (EUR 10,000,000), the cumulative total may be increased to $17,609,000 (EUR 15,000,000) subject to certain provisions, involving sub-licensing the ALPHA-1062 technology and Company the receiving an upfront out-licensing payment of no less than $9,391,000 (EUR 8,000,000). Royalty payments, are determined as follows (collectively the "Galantos Royalty Payments"):
    - 3% of the net sales revenue received by the Company from the sale of any products relating to the ALPHA-1062 Technology;
    - 10% of any sublicensing revenue; and
    - 25% of an upfront payment or milestone payment paid by a sub-licensee to the Company;
- Upon completion of the Galantos Royalty Payments, a royalty payment to NLS of 1% of the revenue received from the ALPHA-1062 Technology by the Company over $100 million per annum; and
- The issuance of a promissory note of $1,400,000 to NLS (Note 6).

The expiration date is twenty years from the Commencement Date (March 15, 2035) or the expiration of the last patent obtained (existing patents extend through 2042) pursuant, whichever event shall last occur, unless earlier terminated pursuant to bankruptcy or insolvency of the licensee; court order against the licensee; or a winding up, liquidation or termination of the existence of the licensee occurs.

During the year ended December 31, 2025, the Company made Galantos Royalty Payments totaling $911,812. At December 31, 2025, accrued Galantos Royalty Payments that remain unpaid totaled $58,962..

On January 1, 2016, the Company assumed NLS's obligations under a Royalty Agreement with Galantos Consulting dated August 31, 2013, which consist of cumulative total payments to Galantos Consulting of $2,348,000 (EUR 2,000,000), the cumulative total may be increased to $3,522,000 (EUR 3,000,000) subject to certain provisions, which is to be paid as follows (collectively the "Galantos Consulting Payments"):

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

The termination date is set as the date at which no further payments of any nature are due.

During the year ended December 31, 2025, the Company made Galantos Consulting Payments totaling $82,232. At December 31, 2025, accrued Galantos Consulting Payments that remain unpaid totaled $19,654.

Legal Proceedings

During the normal course of business, the Company may become involved in legal claims that may or may not be covered by insurance. Management does not believe that any such claims would have a material impact on the Company's consolidated financial statements.

NOTE 17 – SEGMENT INFORMATION

Operating segments are defined as components of the Company for which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), in deciding how to allocate resources and in assessing performance. The Company's CODM is its Chief Executive Officer ("CEO") who views the Company's operations and manages its business as a single reportable operating segment, being the commercial manufacturing and sales of pharmaceutical treatments for neurological diseases in the geographical areas of Canada and the United States of America.

The CEO manages and allocates resources to the operations of the Company on an entity-wide basis. The Company's measure of segment performance is operating loss. Managing and allocating resources on an entity-wide basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources, and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The CEO does not review assets in evaluating the results of the Company, and therefore, such information is not presented.

The following table summarizes the segment's financial information including the Company's significant segment expenses for the years ended December 31:

	2025	2024
Revenue		
Product, net	$ 6,792,024	$ -
Licensing	3,428,251	-
Total revenue	10,220,275	-
Operating Expenses		
Cost of product sales, excluding amortization of intangible asset	474,006	-
Cost of licensing revenue	1,441,317	-
Amortization of intangible asset	21,546	79,875
Research and development:		-
Employee costs	339,302	1,267,662
Grant expenses	81,095	463,881
Stock-based compensation	130,142	358,323
Other	1,317,433	1,830,546
Total research and development	1,867,972	3,920,412
Selling, general and administrative expenses:		
Commercial operations	1,470,717	120,053
Depreciation	37,026	1,345
Employee costs	15,291,592	1,593,742
Sales and marketing	1,812,762	120,973
Stock-based compensation	4,792,383	773,338
Other	5,671,643	5,402,779
Total selling, general and administrative expenses	29,076,123	8,012,230
Total operating expenses	32,880,964	12,012,517
Loss from operations	$ (22,660,689)	$ (12,012,517)

Revenues from customers are attributed to individual countries based on the location of the Company's customer, which is generally determined by the customer's bill-to address. The following table presents revenues from customers by geographic area for the years ended December 31:

	2025	2024
United States	$ 6,792,024	$ -
China	3,428,251	-
Total revenue	**$ 10,220,275**	**$ -**

The geographic location of the Company's long-lived assets as of December 31 was as follows:

	2025	2024
United States	$ 328,540	$ 26,957
Canada	391,423	413,089
Long-lived assets other than financial instruments	**$ 719,963**	**$ 440,046**

NOTE 18 – QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

As discussed in Note 2 of the notes to the consolidated financial statements, the Company identified an error related to the accounting for CAD Options, which were previously classified as equity awards but should have been accounted for as liability-classified awards measured at fair value. The Company will revise its previously reported quarterly financial information based on the summary presented below in its future filings with the SEC, as applicable, to correct for the identified error.

A summary of the corrections to the affected financial statement line items in these condensed consolidated financial statements for each quarterly period of the fiscal year ended December 31, 2025 is presented below.

Consolidated Balance Accounts

	March 31, 2025		
	As Reported	Adjustment	As Revised
Long term liabilities			
Option liabilities	$ -	$ 2,311,047	$ 2,311,047
Total liabilities	$ 7,796,544	$ 2,311,047	$ 10,107,591
Stockholders' equity			
Additional paid-in capital	$ 20,079,465	$ (2,440,654)	$ 17,638,811
Accumulated deficit	(78,291,581)	129,607	(78,161,974)
Total stockholders' equity	40,811,875	(2,311,047)	38,500,828
Total liabilities and stockholders' equity	$ 48,608,419	$ -	$ 48,608,419

	June 30, 2025		
	As Reported	Adjustment	As Revised
Long term liabilities			
Option liabilities	$ -	$ 5,180,509	$ 5,180,509
Total liabilities	$ 13,226,626	$ 5,180,509	$ 18,407,135
Stockholders' equity			
Additional paid-in capital	$ 21,627,035	$ (2,599,841)	$ 19,027,194
Accumulated deficit	(88,780,533)	(2,580,668)	(91,361,201)
Total stockholders' equity	31,896,316	(5,180,509)	26,715,807
Total liabilities and stockholders' equity	$ 45,122,942	$ -	$ 45,122,942

	September 30, 2025		
	As Reported	Adjustment	As Revised
Long term liabilities			
Option liabilities	$ -	$ 3,121,276	$ 3,121,276
Total liabilities	$ 12,387,403	$ 3,121,276	$ 15,508,679
Stockholders' equity			
Common stock	$ 101,826,126	$ (66,683)	$ 101,759,443
Additional paid-in capital	22,290,530	(2,366,379)	19,924,151
Accumulated deficit	(90,098,607)	(688,214)	(90,786,821)
Total stockholders' equity	33,913,810	(3,121,276)	30,792,534
Total liabilities and stockholders' equity	$ 46,301,213	$ -	$ 46,301,213

Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended March 31, 2025			Three Months Ended March 31, 2024		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Operating expenses						
Research and development	$ 407,511	$ (7,095)	$ 400,416	$ 916,716	$ -	$ 16,716
General and administrative expenses	5,365,647	(274,375)	5,091,272	3,474,208	-	3,474,208
Total operating expenses	6,615,086	(281,470)	6,333,616	-	-	4,411,518
Net operating loss	(3,686,432)	281,470	(3,404,962)	-	-	(4,411,518)
Total other income (expenses)	1,679,889	-	1,679,889	(591,193)	-	(591,193)
Net loss and comprehensive loss	$ (2,006,543)	$ 281,470	$ (1,725,073)	$ (5,002,711)	$ -	$ (5,002,711)
Net loss per share, basic and diluted	$ (0.13)	$ 0.02	$ (0.11)	$ (0.87)	$ -	$ -

	Three Months Ended June 30, 2025			Three Months Ended June 30, 2024		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Operating expenses						
Research and development	$ 317,120	$ 89,020	$ 406,140	$ 967,200	$ -	$ 967,200
Selling, general and administrative expenses	6,538,085	2,621,256	9,159,341	1,434,251	-	1,434,251
Total operating expenses	7,394,688	2,710,276	10,104,964	2,421,211	-	2,421,211
Net operating loss	(5,737,001)	(2,710,276)	(8,447,277)	(2,421,211)	-	(2,421,211)
Total other income (expenses)	(4,751,951)	-	(4,751,951)	305,699	-	305,699
Net loss and comprehensive loss	$ (10,488,952)	$ (2,710,276)	$ (13,199,228)	$ (2,115,512)	$ -	$ (2,115,512)
Net loss per share, basic and diluted	$ (0.65)	$ (0.17)	$ (0.82)	$ 0.35	$ -	$ 0.35

	Six Months Ended June 30, 2025			Six Months Ended June 30, 2024		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Operating expenses						
Research and development	$ 724,631	$ 81,925	$ 806,556	1,883,916	$ -	$ 1,883,916
Selling, general and administrative expenses	12,239,357	2,346,881	14,586,238	4,908,459	-	4,908,459
Total operating expenses	14,009,774	2,428,806	16,438,580	6,832,729	-	6,832,729
Net operating loss	(9,423,433)	(2,428,806)	(11,852,239)	(6,832,729)	$ -	(6,832,729)
Total other income (expenses)	(3,072,062)	$ -	$ (3,072,062)	(285,494)	$ -	(285,494)
Net loss and comprehensive loss	$ (12,495,495)	$ (2,428,806)	$ (14,924,301)	(7,118,223)	$ -	$ (7,118,223)
Net loss per share, basic and diluted	$ (0.78)	$ (0.15)	$ (0.93)	(1.21)	$ -	$ (1.21)

	Three Months Ended September 30, 2025			Three Months Ended September 30, 2024		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Operating expenses						
Research and development	$ 573,592	$ (59,809)	$ 513,783	$ 996,029	$ -	$ 996,029
Selling, general and administrative expenses	6,945,804	(1,832,645)	5,113,159	1,471,994	-	1,471,994
Total operating expenses	8,152,844	(1,892,454)	6,260,390	2,487,784	-	2,487,784
Net operating loss	(5,311,986)	1,892,454	(3,419,532)	(2,487,784)	-	(2,487,784)
Total other income (expenses)	3,993,912	-	3,993,912	627,878	-	627,878
Net loss and comprehensive loss	$ 1,318,074)	$ 1,892,454	$ 574,380	$ (1,859,906)	$ -	$ (1,859,906)
Net loss per share, basic	$ (0.08)	$ 0.12	$ 0.04	$ (0.31)	$ -	$ (0.31)
Net loss per share, diluted	$ (0.30)	$ 0.01	$ (0.29)	$ (0.31)	$ -	$ (0.31)

	Nine Months Ended September 30, 2025			Nine Months Ended September 30, 2024		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Operating expenses						
Research and development	$ 1,298,223	$ 22,116	$ 1,320,339	$ 2,879,945	$ -	$ 2,879,945
Selling, general and administrative expenses	19,185,161	514,236	19,699,397	6,380,453	-	6,380,453
Total operating expenses	22,162,618	536,352	22,698,970	9,320,513	-	9,320,513
Net operating loss	(14,735,419)	(536,352)	(15,271,771)	(9,320,513)	-	(9,320,513)
Total other income (expenses)	921,850	-	921,850	342,384	$ -	342,384
Net loss and comprehensive loss	$ (13,813,569)	$ (536,352)	$ (14,349,921)	$ (8,978,129)	$ -	$ (8,978,129)
Net loss per share, basic	$ (0.86)	$ (0.03)	$ (0.89)	$ (1.51)	$ -	$ (1.51)
Net loss per share, diluted	$ (0.87)	$ (0.02)	$ (0.89)	$ (1.51)	$ -	$ (1.51)

Consolidated Statements of Stockholders' Equity

For the three months ended March 31, 2025

	Additional Paid in Capital			Accumulated Deficit			Total		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Balance, December 31, 2024	$ 18,724,092	$ (2,216,355)	$ 16,507,737	$ (76,285,038)	$ (151,863)	$ (76,436,901)	$ 41,463,045	$ (2,368,218)	$ 39,094,827
Stock-based compensation	$ 1,355,373	$ (224,299)	$ 1,131,074	$ -	$ -	$ -	$ 1,355,373	$ (224,299)	$ 1,131,074
Net loss	$ -	$ -	$ -	$ (2,006,543)	$ 281,470	$ (1,725,073)	$ (2,006,543)	$ 281,470	$ (1,725,073)
Balance, March 31, 2025	**$ 20,079,465**	**$ (2,440,654)**	**$ 17,638,811**	**$ (78,291,581)**	**$ 129,607**	**$ (78,161,974)**	**$ 40,811,875**	**$ (2,311,047)**	**$ 38,500,828**

For the three months ended June 30, 2025

	Additional Paid in Capital			Accumulated Deficit			Total		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Balance, March 31, 2025	$ 20,079,465	$ (2,440,654)	$ 17,638,811	$ (78,291,581)	$ 129,607	$ (78,161,974)	$ 40,811,875	$ (2,311,047)	$ 38,500,828
Stock-based compensation	$ 1,547,570	$ (159,187)	$ 1,388,383	$ -	$ -	$ -	$ 1,547,570	$ (159,187)	$ 1,388,383
Net loss	$ -	$ -	$ -	$ (10,488,952)	$ (2,710,275)	$ (13,199,227)	$ (10,488,952)	$ (2,710,275)	$ (13,199,227)
Balance, June 30, 2025	**$ 21,627,035**	**$ (2,599,841)**	**$ 19,027,194**	**$ (88,780,533)**	**$ (2,580,668)**	**$ (91,361,201)**	**$ 31,896,316**	**$ (5,180,509)**	**$ 26,715,807**

For the six months ended June 30, 2025

	Additional Paid in Capital			Accumulated Deficit			Total		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Balance, December 31, 2024	$ 18,724,092	$ (2,216,355)	$ 16,507,737	$ (76,285,038)	$ (151,863)	$ (76,436,901)	$ 41,463,045	$ (2,368,218)	$ 39,094,827
Stock-based compensation	$ 2,902,943	$ (383,486)	$ 2,519,457	$ -	$ -	$ -	$ 2,902,943	$ (383,486)	$ 2,519,457
Net loss	$ -	$ -	$ -	$ (12,495,495)	$ (2,428,805)	$ (14,924,300)	$ (12,495,495)	$ (2,428,805)	$ (14,924,300)
Balance, June 30, 2025	**$ 21,627,035**	**$ (2,599,841)**	**$ 19,027,194**	**$ (88,780,533)**	**$ (2,580,668)**	**$ (91,361,201)**	**$ 31,896,316**	**$ (5,180,509)**	**$ 26,715,807**

For the three months ended September 30, 2025

	Common Stock			Additional Paid in Capital			Accumulated Deficit			Total		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Balance, June 30, 2025	$ 99,154,053	$ -	$ 99,154,053	$ 21,627,035	$ (2,599,841)	$19,027,194	$(88,780,533)	$ (2,580,668)	$(91,361,201)	$ 31,896,316	$ (5,180,509)	$26,715,807
Options exercised	$ 775,190	$ (66,683)	$ 708,507	$ (410,585)	$ 409,961	$ (624)	$ -	$ -	$ -	$ 364,605	$ 343,278	$ 707,883
Stock-based compensation	$ -	$ -	$ -	$ 1,074,080	$ (176,499)	$ 897,581	$ -	$ -	$ -	$ 1,074,080	$ (176,499)	$ 897,581
Net loss	$ -	$ -	$ -	$ -	$ -	$ -	$ (1,318,074)	$ 1,892,454	$ 574,380	$ (1,318,074)	$ 1,892,454	$ 574,380
Balance, September 30, 2025	**$101,826,126**	**$ (66,683)**	**$101,759,443**	**$ 22,290,530**	**$ (2,366,379)**	**$19,924,151**	**$(90,098,607)**	**$ (688,214)**	**$(90,786,821)**	**$ 33,913,810**	**$ (3,121,276)**	**$30,792,534**

For the nine months ended September 30, 2025

	Common Stock			Additional Paid in Capital			Accumulated Deficit			Total		
	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised	As Reported	Adjustment	As Revised
Balance, December 31, 2024	$ 99,128,230	$ -	$ 99,128,230	$ 18,724,092	$ (2,216,355)	$16,507,737	$(76,285,038)	$ (151,863)	$(76,436,901)	$ 41,463,045	$ (2,368,218)	$ 39,094,827
Options exercised	$ 775,190	$ (66,683)	$ 708,507	$ (410,585)	$ 409,961	$ (624)	$ -	$ -	$ -	$ 364,605	$ 343,278	$ 707,883
Stock-based compensation	$ -	$ -	$ -	$ 3,977,023	$ (559,985)	$ 3,417,038	$ -	$ -	$ -	$ 3,977,023	$ (559,985)	$ 3,417,038
Net loss	$ -	$ -	$ -	$ -	$ -	$ -	$(13,813,569)	$ (536,351)	$(14,349,920)	$(13,813,569)	$ (536,351)	$(14,349,920)
Balance, September 30, 2025	**$101,826,126**	**$ (66,683)**	**$101,759,443**	**$ 22,290,530**	**$ (2,366,379)**	**$19,924,151**	**$(90,098,607)**	**$ (688,214)**	**$(90,786,821)**	**$ 33,913,810**	**$ (3,121,276)**	**$ 30,792,534**

Consolidated Statements of Cash Flows

	Three Months Ended March 31, 2025		
	As Reported	Adjustment	As Revised
Net loss	$ (2,006,543)	$ 281,470	$ (1,725,073)
Cash flow used in operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	$ 1,355,373	$ (281,470)	$ 1,073,903

	Six Months Ended June 30, 2025		
	As Reported	Adjustment	As Revised
Net loss	$ (12,495,495)	$ (2,428,806)	$ (14,924,301)
Cash flow used in operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	$ 2,902,943	$ 2,428,806	$ 5,331,749

	Nine Months Ended September 30, 2025		
	As Reported	Adjustment	As Revised
Net loss	$ (13,813,569)	$ (536,352)	$ (14,349,921)
Cash flow used in operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	$ 3,977,023	$ 536,352	$ 4,513,375

NOTE 19 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events through March 30, 2026, the date these financial statements were issued, for events that should be recorded or disclosed in the financial statements for the year ended December 31, 2025. The Company concluded that no other events have occurred that would require recognition or disclosure in the financial statements.

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