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

FORM 10-K

☒ **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: 001-41429

PROMIS NEUROSCIENCES INC.

(Exact name of registrant as specified in its charter)

Ontario, Canada	**98-0647155**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
Suite 200, 1920 Yonge Street Toronto, Ontario	**M4S 3E2**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (416) 847-6898

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name Of Each Exchange On Which Registered**
Common Shares, No Par Value per Share	**PMN**	**The Nasdaq Capital Market**

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

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 the 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 §239.90D-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 ☒

Based on the closing price as reported on the Nasdaq Capital Market, the aggregate market value of the Registrant's Common Stock held by non-affiliates on June 30, 2025, the last day of its most recently completed second fiscal quarter, was approximately $29.7 million. Shares of Common Stock held by each executive officer and director and by each shareholder affiliated with a director or an executive officer have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding Common Shares of the Registrant as of March 25, 2026 was 8,967,693.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 annual meeting of shareholders, or the 2026 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2026 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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SUMMARY OF THE MATERIAL AND OTHER RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks are described more fully in Item 1A – "Risk Factors" and include, but are not limited to, the following:

Risks Related to the Development of Our Product Candidates

- Our product candidates are still in the early stages of development and there is significant uncertainty that any such products will be approved.
- We have concentrated a portion of our research and development efforts on the treatment of Alzheimer's Disease, a field that has seen very limited success in drug development.
- Our business is heavily dependent on the successful development, regulatory approval and commercialization of PMN310 and any future product candidates that we may develop or acquire, including PMN442 and PMN267.
- Clinical and nonclinical drug development involves a lengthy, expensive and uncertain process. The results of nonclinical studies and early clinical trials are not always predictive of future results. PMN310 or any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- Interim, "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more data become available and is subject to audit and verification procedures that could result in material changes in the final data.
- We cannot be certain that PMN310, PMN442, PMN267 or any of our future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

Risks Related to Our Financial Position and Capital Needs

- We have incurred losses since inception, we anticipate that we will incur continued losses for the foreseeable future and will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We have no product candidates approved for commercial sale, we have never generated any revenue from product sales and we may never be profitable.

Risks Related to the Commercialization of Our Product Candidates

- The market opportunities for PMN310, PMN442, PMN267, and future product candidates, if approved, may be smaller than we anticipate.
- Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of adoption and use by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.
- Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process to commercialize our potential products, which may not be successful.

Risks Related to Our Dependence on Third Parties

- We will rely on third parties to supply components, research, develop, test, and manufacture our product candidates and market, if approved. The loss of any of these third-party relationships or the failure of any of them to meet their obligations to us could affect our ability to develop and obtain approval of our product candidates in a timely manner.
- If any of our third-party manufacturers encounter difficulties in production of PMN310, PMN267, PMN442 or any future product candidate we develop, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or, if approved, for commercial sale could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Risks Related to Our Intellectual Property

- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates, and other proprietary technologies if approved, may be adversely affected.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through in-licenses.

Risks Related to Legal and Regulatory Compliance Matters

- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize future product candidates, and our ability to generate revenue be materially impaired.
- Even if we obtain regulatory approval for PMN310, PMN442, PMN267 or any future product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Risks Related to Our Business and Industry

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

Risks Related to Ownership of Our Common Shares and Our Status as a U.S. Public Company

- Investment in our Common Shares is speculative, involves risk, and there is no guarantee of a return.
- The price of our Common Shares may be volatile.
- Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other shareholders.
- There is no active market for our warrants and pre-funded warrants.

General Risk Factors

- The elimination of monetary liability against our directors, officers, and employees under Canadian law and the existence of indemnification rights for our obligations to our directors, officers, and employees may result in substantial expenditures by us and may discourage lawsuits against our directors, officers, and employees.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report includes statements that express ProMIS' opinions, expectations, beliefs, plans, objectives, assumptions, or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." These forward-looking statements can generally be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "seeks," "projects," "intends," "plans," "may," "will," or "should" or, in each case, their negative or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs or current expectations concerning, among other things, results of operations, financial condition, liquidity, our ability to continue as a going concern, patent term expiration dates, prospects, growth, strategies and the markets in which ProMIS operates. Such forward-looking statements are based on available current market material and management's expectations, beliefs and forecasts concerning future events impacting ProMIS. Factors that may impact such forward- looking statements include:

- the anticipated amount, timing and accounting of contingent, milestone, royalty and other payments under licensing or collaboration agreements;
- tax positions and contingencies; research and development costs; compensation and other selling, general and administrative expense;
- foreign currency exchange risk;
- estimated fair value of assets and liabilities;
- the potential impact of increased competition in the markets in which we compete;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- our plans and investments in our portfolio as well as implementation of our corporate strategy;
- the risk that we will maintain enough liquidity to execute our business plan and our ability to continue as a going concern;
- our expected use of proceeds from sales of our common shares or common share equivalents in offerings or "at-the-market" offerings and the period over which such proceeds, together with existing cash, will be sufficient to meet our operating needs;
- the drivers for growing our business, including our plans and intention to commit resources relating to discovery, research and development programs and business development opportunities as well as the potential benefits and results of, and the anticipated completion of, certain business development transactions;
- the expectations, development plans and anticipated timelines, including costs and timing of clinical trials, filings and approvals, of our products candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline product candidates, if approved;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the direct and indirect impact of health crises on our business and operations, including expenses, the supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, research and development costs, clinical trials and employees;

- the impact of global financial, economic, political and health events, such as rising inflation, market volatility, fluctuating interest rates, capital markets disruptions, legislative action, possible government shutdowns and international tariffs;
- the potential impact of healthcare reform in the United States and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our product candidates, if approved;
- the impact of the continued uncertainty of the credit and economic conditions in certain countries and our collection of accounts receivable in such countries;
- the risk that we become characterized as a passive foreign investment company;
- our ability to prevent and successfully remediate any significant deficiencies or material weaknesses in internal controls over financial reporting;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations; and
- the impact of new laws (including tax and tariff policies), executive orders, regulatory requirements, judicial decisions and accounting standards.

The forward-looking statements contained in this Annual Report on Form 10-K are based on ProMIS' current expectations and beliefs concerning future developments and their potential effects on ProMIS. There can be no assurance that future developments affecting ProMIS will be those that ProMIS has anticipated. These forward-looking statements involve a number of risks, uncertainties, some of which are beyond ProMIS' control, or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of the assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Moreover, the occurrence of the events described in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K may adversely affect ProMIS. ProMIS will not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

PART I

Item 1. Business

Overview

ProMIS has in-licensed a patented technology platform with the potential to deliver a portfolio of antibody therapies, therapeutic vaccines, and other therapies derived from antibodies for neurodegenerative diseases and other misfolded protein diseases, which may include Alzheimer's disease, multiple system atrophy, amyotrophic lateral sclerosis, frontotemporal lobar degeneration, Parkinson's disease, progressive supranuclear palsy, corticobasal degeneration (respectively, AD, MSA, ALS, FTLD, PD, PSP, CBD) and schizophrenia. A common biologic cause contributes to each of these conditions, in that certain proteins, which normally perform a needed function, when misfolded, can cause neuronal degeneration and death, contributing to morbidity and mortality. ProMIS' technology platform is an example of the advances in drug discovery enabled by computational power, in silico discovery, and/or artificial intelligence. We believe this platform provides a potential advantage by selectively targeting the toxic misfolded proteins with therapeutics.

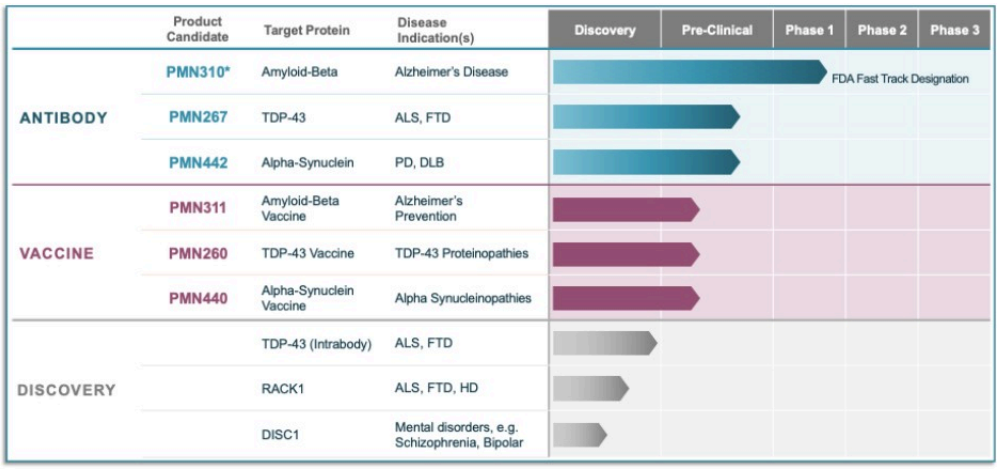
ProMIS' EpiSelect™ Platform Technology

ProMIS' scientific foundation is centered on the growing knowledge base relating to diseases characterized by the presence of abnormal, misfolded proteins. Genetic and experimental research in the neuroscience community has demonstrated that propagating, neurotoxic, misfolded proteins (also referred to as prion-like particles or toxic soluble oligomers) are fundamental drivers of multiple neurodegenerative diseases, including AD, MSA, and ALS. ProMIS' EpiSelect™ platform technology allows for the identification of conformational epitopes that become exposed on toxic, misfolded forms of a given protein but are not present on the properly folded form of the same protein. Such disease-specific epitopes (DSEs) can then be used to generate therapeutic antibody candidates that selectively target toxic forms of the protein without interfering with essential functions of the healthy protein.

The ability to model protein misfolding *in silico* to predict target epitopes restricted to toxic, misfolded forms of a protein was a transformational advance for the development of therapeutic antibodies in terms of speed and quality of the antibodies generated. Earlier methods using less defined immunogens, such as synthetic protein aggregates, relied on chance and extensive screening to identify promising antibody clones, and could never quite achieve strict selectivity for the toxic, misfolded protein. The Company first licensed exclusive rights to ProMIS™ target epitope identification technology from the University of British Columbia (UBC) to predict novel DSEs on the molecular surface of misfolded proteins. ProMIS™ is an "in silico" rational selection approach that could be applied to any protein where the normal folding structure is at least partially known. The Company subsequently acquired a worldwide license from UBC to EpiSelect™ a computational algorithm that supersedes ProMIS™, employing thermodynamics and statistical mechanics to model protein misfolding. This proprietary computational discovery platform provides a unique and robust engine to predict DSEs on the molecular surface of misfolded proteins. The amino acid sequence of the toxic, misfolded form and the healthy, properly folded form of a target protein are the same but they differ in their conformation. The ProMIS platform offers the ability to identify targets (conformational epitopes) unique to the toxic, misfolded form. Cyclic peptides containing the conformational epitopes are created and used to immunize mice or rabbits to generate selective monoclonal antibodies (mAbs) that are designed to attack the disease-causing form of the protein without interfering with the healthy form of the same protein. The mAbs raised in animals are humanized (the critical binding regions are inserted into a human antibody framework) for potential use in patients. We believe the ProMIS approach has the potential to produce more effective and safer antibodies compared to traditional methods of immunization with whole proteins/peptides or aggregates which result in pan-reactive antibodies that cross-react with all forms of a target protein. The lack of selectivity of such antibodies dilutes their efficacy by binding to non-toxic forms of the protein and can potentially interfere with the function of the properly folded protein.

Our Pipeline

We are developing a pipeline of antibodies aimed at selectively targeting misfolded toxic forms of proteins that drive neurodegenerative diseases without interfering with the essential functions of the same properly folded proteins.



Arrows denote the stage of each program

ALS: Amyotrophic lateral sclerosis, FTD: Frontotemporal dementia, PD: Parkinson's disease, DLB: Dementia with Lewy bodies, HD: Huntington's disease

ProMIS' Objectives for 2026

The Company plans to pursue the following key objectives for 2026:

- Progression of the PRECISE-AD Phase 1b trial of PMN310 for Alzheimer's disease, maintaining rigorous execution and data integrity. Based on current clinical trial patient visit schedules, the Company expects to complete the six-month assessments in the second quarter of 2026, with the blinded interim analysis anticipated in early third quarter 2026. Completion of dosing and all patient visits is expected in the fourth quarter of 2026, with top-line data anticipated in early 2027 following database lock and statistical analysis.

- Strategic Growth and Corporate Visibility: Enhance corporate awareness by engaging strategically with investors and industry stakeholders, while evaluating partnership and business development opportunities that underscore the value of the company's pipeline.

- Operational Readiness for Future Success: Strengthen organizational infrastructure and capabilities to support potential clinical milestones and position the company for long-term growth.

PRODUCT CANDIDATES

Development of a Therapy for the Treatment of Alzheimer's Disease (AD)

AD Overview

AD, a progressive neurodegenerative disease, is the most common type of dementia, accounting for approximately 60 – 80% of all dementia cases. Early symptoms of AD include recent memory loss, as well as apathy and depression. As the disease progresses inexorably, language deterioration, impaired ability to mentally manipulate visual information, poor judgment, confusion, restlessness, and profound mood swings develop. Eventually AD destroys cognition, personality, and the ability to function. The early symptoms of AD, especially at the inaugural stage of mild cognitive impairment

(MCI), are often missed because they are frequently and mistakenly taken for natural signs of ageing. In 2020, reports concluded that 50% of primary care physicians believed the medical profession was not prepared to meet the expected increase in demands the projected rise in AD and dementia cases will create.

During 2024, it was estimated there were 6.9 million Americans 65 and older living with AD, and that number is projected to rise to 12.7 million by 2050 (www.alz.org, Alzheimer's disease Facts and Figures 2024). In the United States, one in three seniors dies of AD or another dementia, which kills more people than breast cancer and prostate cancer combined. AD is the sixth leading cause of death in the United States, according to the Alzheimer's Association. In 2023, AD and other dementias cost the U.S. $592 billion, and those costs are projected to rise with the increasing number of patients. Approximately 11 million Americans are reported to be unpaid caregivers, who in 2022 provided support for patients valued at $339 billion, to people with AD and other dementias.

Historically, a major challenge in AD has been diagnosis. Twenty years ago, diagnosis of AD could only be confirmed by autopsy. Consensus guidelines have since been developed that established new diagnostic criteria — A/T/N. The methods used are based on sophisticated approaches to brain imaging: amyloid positron emission tomography (PET) scans measuring amyloid plaque as a proxy for pathology, tau PET scans measuring tau tangles as a proxy for pathology, and cortical magnetic resonance imaging measuring cortical atrophy as a measure of neurodegeneration. Each of these tests costs thousands of dollars, affordable perhaps to diagnose patients for a clinical trial, but not practical for screening millions of people who might be at risk or have pre-symptomatic AD.

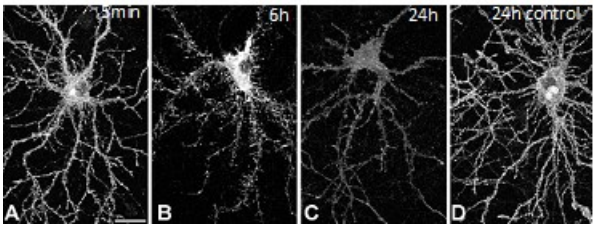
There are now blood-based biomarkers (diagnostic assays) that can provide information that correlates with expensive A/T/N imaging. Plasma levels of ptau 217 and ptau 181 (tau protein phosphorylated at amino acids 217 and 181 respectively) correlate with brain imaging measures, AD diagnosis, and disease progression (Mattson et al. JAMA 2023, Jack et al. Brain 2023, Therriant et al. JAMA 2023). These advances have implications for ProMIS' strategy. Better diagnostics can facilitate more efficient clinical trials, both in terms of identifying potential subjects for the trial and also detecting a potential treatment effect in early, small trials. Secondly, the ability to diagnose disease prior to symptoms raises the possibility of preventive treatment.

According to the World Alzheimer Report 2022, the current dementia market comprises two product categories, namely, AChE inhibitors and N-methyl-D-aspartate receptor antagonists. AChE inhibitors dominate the market. The overall market is dominated by four leading brands — Aricept, Namenda, Exelon and Ebixa. Aricept, whose active ingredient is an AChE inhibitor, holds the largest market share. North America was the largest market for AD drugs in 2019, accounting for approximately 35% of total worldwide AD pharmaceutical sales in that year. Three mAbs (Aduhelm, Leqembi, Kisunla) were approved from 2021 to 2024, which creates a third category of marketed AD treatments, and the first to be considered disease modifying. Aduhelm was approved in 2021 under the U.S. Food and Drug Administration's (FDA) Accelerated Approval pathway but commercialization was discontinued in January 2024. Leqembi and Kisunla received traditional approval in 2023 and 2024, respectively.

Although there is no scientific consensus on the causation of AD or method of action to treat AD, evidence from some genetic and preclinical studies suggests a causative role for Aβ in the pathogenesis of AD. Published genetic studies support a direct link between increased levels of Aβ and disease susceptibility. Research suggests that genetic mutations in the Aβ precursor protein (APP) and in the presenilin 1 and 2 genes responsible for familial forms of early onset AD all result in increased production of Aβ and Aβ aggregates (*Citron et al, 1992; Borchelt et al, 1996*). Down Syndrome patients with three copies of the APP gene on chromosome 21 also have elevated levels of APP and Aβ deposits and often develop AD at a premature age (*Podlisny et al, 1987*). Aβ brain concentration can also increase due to age associated reduction of clearance. Along the same lines, the APOE4 allele, which has been linked to an increased risk of late onset AD, is associated with increased Aβ deposit, while the APOE2 allele, which has been linked to a decreased risk, is associated with decreased Aβ levels (*Holtzman et al, 2012*). Finally, the only known protective mutation against AD is found in the APP gene and research suggests that this leads to a reduction in the formation of Aβ (*Jonsson et al, 2012*). In a preclinical study, it was reported that intracerebral injection of Aβ-containing brain extracts from human AD patients into susceptible mice induced cerebral amyloidosis and associated pathology. Depletion of Aβ from the extracts reversed this activity, supporting a link between Aβ and disease induction (*Meyer-Luehmann et al, 2006*).

While the presence of Aβ plaque is a distinguishing feature of AD, there is a growing body of scientific evidence that the synaptic loss and neurodegenerative spread of AD is primarily mediated by soluble oligomers of misfolded Aβ rather than plaque (*Cleary et al, 2004; Jin et al, 2011*). Reports from several groups indicate that plaque burden correlates poorly with memory impairment (*Cleary et al, 2004; Ferreira et al, 2015*) and insoluble Aβ fibrils show little or no demonstrable toxicity *in vitro* or *in vivo* (*Balducci et al, 2010; Shankar et al, 2008*). In contrast, a significant correlation between disease severity and levels of soluble Aβ in the central nervous system was reported by Lue et al (*Lue et al, 1999*), and the direct neurotoxicity of soluble Aβ oligomers was demonstrated in neuronal cultures in vitro by separate groups (*Lauren et al, 2009; Jin et al, 2011*). In published reports using rodent models, the injection of soluble oligomeric Aβ, but not soluble monomers or plaque, was shown to induce synaptic damage and cognitive dysfunction (*Cleary et al, 2005; Hong et al, 2016).*

Figure 1



Synaptotoxicity of Ab oligomers on hippocampal neurons in vitro (*Lacor et al, 2007, J Neuroscience*)

The mechanism by which soluble oligomeric Aβ generates neuronal damage contributing to AD has been well-studied. A convergence of evidence from multiple studies suggests that the progressive nature of AD arises from the formation and spread of a prion-like subset of misfolded oligomers of Aβ that adopt a β-sheet-rich conformation transmissible to native Aβ in a template-like manner. The self-propagation of these prion-like oligomers follows the stereotypical progression of AD, with initial involvement of the enthorhinal cortex followed by spreading to the hippocampus and neocortex as described by Khan et al (*Khan et al, 2014*). The prion-like spread of Aβ oligomers has been well-documented in animal models by different groups following the injection of purified oligomers or brain extracts from AD patients or diseased animals (*Cleary et al, 2005; Meyer-Luehmann et al, 2006; Watts et al, 2014; Hong et al, 2016*). There is also *in vitro* evidence that such misfolded "Aβ prions" from AD brain can catalyze the misfolding and hyperphosphorylation of tau, another protein involved in the pathogenesis of AD as reported by Jin et al (*Jin et al, 2011*). Targeting of Aβ oligomers therefore represents an attractive strategy to inhibit progression of the neurodegenerative Aβ-tau cascade (*Choi et al, 2015; Khan et al, 2014*).

PMN310

ProMIS' lead therapeutic program is PMN310, a mAb designed to treat AD by selectively targeting the toxic misfolded form of Aβ. Based on the understanding of Aβ biology described above, PMN310 was designed to be more selective for the toxic oligomer of amyloid than other anti-Aβ antibodies such as aducanumab from Biogen, lecanemab, co-developed by Eisai Co. and Biogen, donanemab from Lilly, ACU193 from Acumen and the Prothena PRX012 antibody. These antibodies bind oligomers, which could account for the efficacy seen by the marketed drugs, but they also appear to bind plaque, which may result in a higher incidence of ARIA (E and H). This off-target binding of plaque may limit the benefit of treatment by both limiting the highest dose that can be safely administered and by "wasting" a substantial portion of the administered antibody which binds plaque, reducing what is available to neutralize the toxic oligomers.

Recent clinical trial results show that antibodies that bind Aβ monomers (bapineuzumab, solanezumab, crenezumab, gantenerumab) are not efficacious in AD (*Salloway et al, 2014, NEJM; Carlson et al, 2016, Alzheimer's and Dementia; Ostrowitzki et al, 2022, JAMA Neurol;https://www.roche.com/media/releases/med-cor-2022-11-14*), suggesting that high selectivity for low abundance toxic AβO is desirable to prevent mAbs from being consumed by unproductive binding to non-pathogenic, abundant monomers (target distraction). Other antibodies with reduced binding to monomers and more

selectivity for aggregated Aβ have produced more promising results, including aducanumab (Aduhelm), lecanemab (Leqembi) and donanemab (Kisunla), which received approval from the FDA. However, treatment with all of these antibodies was associated with the dose-limiting adverse events of ARIA-E (brain edema) and ARIA-H (microhemorrhages) correlated with binding to insoluble deposits of Aβ in the vasculature and plaque. We believe that a selective, oligomer-specific antibody that does not bind monomers or plaque could circumvent these issues and potentially provide an improved product profile with enhanced efficacy. Results of our analysis of the binding response of Aβ-directed antibodies were presented at the Alzheimers's Association International Conference and the American Academy of Neurology in 2023 and published in 2025 (*Kaplan et al, 2025, Alzheimer's Dement. 2025,* http://dx.doi.org/10.1002/trc2.70184). All antibodies showed some binding signal to toxic AβO from human brain extracts but target distraction by monomers abolished or reduced binding. Only the antibodies that retained measurable binding to oligomers (aducanumab, donanemab and lecanemab) in the face of competition by monomers have shown improvement on cognitive endpoints in previous clinical trials, and that improvement was modest. In our analysis, PMN310 avoided monomer target distraction, with the smallest percent inhibition of binding to brain oligomers when compared to other Aβ-directed antibodies. We believe these data support the therapeutic potential of PMN310.

Development of PMN310 began with using the ProMIS computational platform, which produced *in silico* six different conformational epitopes as potential targets exposed on toxic misfolded AβO but not Aβ monomers or plaque. The use of AbO-restricted epitopes as the immunogen to generate antibodies is drastically different from the conventional immunization methods used by others. Immunization with Ab peptide or synthetic aggregates used by others to generate Ab-directed antibodies virtually always results in non-selective antibodies that react not only with oligomers but also to varying degrees with monomers and plaque. In contrast, mAbs raised against cyclic peptides containing our predicted AbO conformational epitopes displayed selectivity for Aβ oligomers vs monomers or plaque, and inhibited AβO toxicity and propagation *in vitro*. The Company designated the PMN310 antibody as its lead candidate for development in AD. As described in our published preclinical studies (*Gibbs et. al., 2019, Scientific Reports*), PMN310 displayed the desired selective profile with binding to synthetic AβO and little or no binding to Aβ monomers as determined by surface plasmon resonance (SPR), and no detectable binding to plaque or vascular deposits in AD brain sections as determined by immunohistochemistry (IHC). In SPR studies with brain extracts from multiple individuals who died of AD, PMN310 also showed binding to fractions containing the toxic AbO species suggesting that PMN310 can recognize an AβO epitope shared across AD brains. *In vitro*, PMN310 inhibited AβO propagation in a thioflavin-T (ThT) based assay measuring the formation of Aβ aggregates with a beta-sheet structure over time (*Gibbs et al, 2019, Scientific Reports*). PMN310 also reduced the killing of primary mouse neurons by toxic AβO in culture (Fig.1). *In vivo*, the activity of murine PMN310 was tested in two different models. In one model conducted at SynAging (Vandoeuvre-les-Nancy, France), PMN310 and a preparation of toxic AβO were co-delivered (mAb:AβO ratio of 2:1) by intracerebroventricular (ICV) injection into male, 3-month old, wild-type C57Bl6/J mouse to determine whether PMN310 might improve cognitive performance and molecular markers in this model of AβO-induced neurotoxicity. Treatment groups consisted of day 0 ICV injection of vehicle alone, AβO alone, vehicle with PMN310 or AβO with PMN310, and contained 12 mice per group to achieve statistical significance. Cognitive performance was assessed on days 7 – 8 using the novel object recognition (NOR) assay. Mice were sacrificed and perfused on day 10, the hippocampus was isolated and levels of synaptic (PSD-95, SNAP25) and inflammation (TNF-α) markers were measured by ELISA in hippocampal homogenates from individual mice. AβO-injected mice failed to recognize a new object and displayed a discrimination index of 0 or less. Co-injection of PMN310 with the toxic oligomers prevented this cognitive deficit. As expected, ICV injection of PMN310 alone had no effect (Fig. 2). The cognitive deficit induced by ICV injection of AβO was associated with inflammation and synaptic damage in the hippocampus, a region important in the development of memory. Hippocampal homogenates from AβO-treated mice displayed an increase in levels of TNF-α and decreases in PSD-95 and SNAP25. Partial protection from these changes was observed in mice co-injected with synthetic AβO and PMN310.

Figure 2

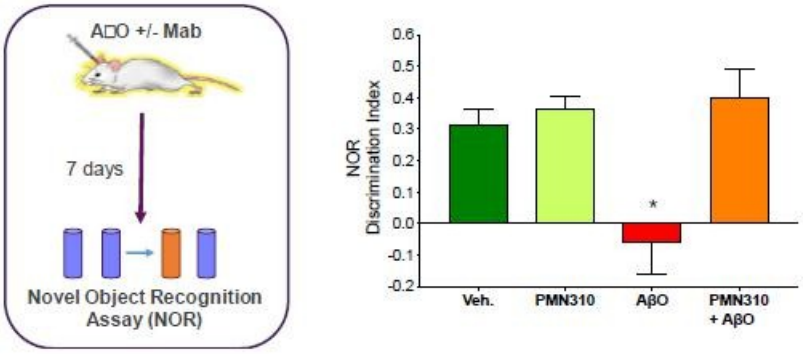


Fig. 2. Administration of PMN310 to mice prevented the loss of short-term memory formation caused by toxic AβO.

*p<0.05 vs Vehicle, #p<0.05 vs AβO. Discrimination index = (time exploring new object – time exploring familiar object)/total exploration time.

In a second *in vivo* model conducted at reMYND (Leuven, Belgium), the potential effect of treatment with murine PMN310 (mouse IgG2a) was tested in the transgenic (Tg) hAPP[V717I] mouse model of AD. Characterization of the model indicates that these hAPP-Tg mice display spontaneous, progressive accumulation of Aβ in the brain, eventually resulting in amyloid plaques around 10-11 months of age. In the pre-plaque stage of the pathology, there is a clear cognitive and long-term synaptic potentiation (LTP) deficit in these mice suggesting that impairment is caused by soluble toxic species such as AβO rather than plaque. The aim of the study was to assess the impact of seven weekly doses of PMN310 administered intraperitoneally (i.p.) at 30 mg/kg to female mice, beginning at 5.0 months of age. Experimental groups consisted of hAPP-Tg mice treated with vehicle or PMN310, and non-Tg, age-matched littermates treated with vehicle as a control, with 17 mice per group to achieve statistical significance. Spatial learning and memory performance were assessed using the Morris Water Maze task at 6.4 months of age (after seven doses of antibody) which measures the ability of mice to learn and remember the location of a hidden platform in a pool of water. Compared to non-Tg littermates, the hAPP-Tg mice were significantly impaired and showed an increase in both escape latency (time required to find the hidden platform, p=0.0024) and the search path or distance traveled to reach the platform (p=0.0047). Treatment of hAPP-Tg mice with PMN310 significantly improved these outcomes with a decrease in escape latency (p=0.0187) and search path (p=0.0071) (Fig. 3).

Figure 3

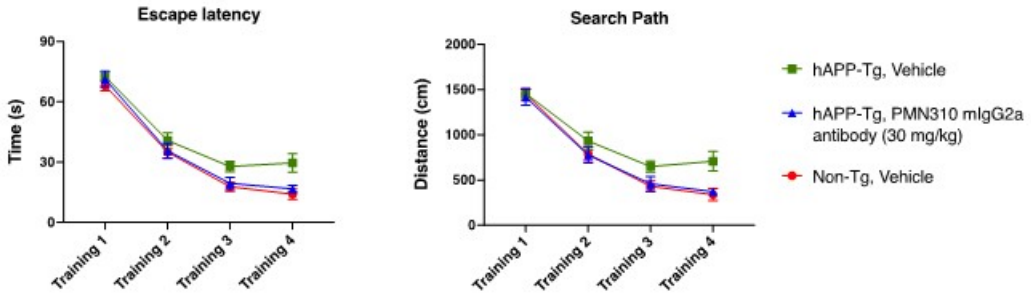


Fig. 3. Systemic administration of PMN310 provides a cognitive benefit in a mouse model of AD (hAPP[V717I] Tg mice)

PMN310 brain exposure and kinetics after systemic i.p. administration were assessed in mice (*Gibbs et. al., 2019, Scientific Reports*). The results suggested that PMN310 is comparable to other therapeutic mAbs and is able to cross the blood-brain barrier to reach its target, an observation supported by the human Phase 1a trial. The Company believes that the greater selectivity of PMN310 for AβO may result in greater neutralization of this disease-causing species (no target distraction) compared with Aβ antibodies derived from immunization with synthetic aggregates. By avoiding plaque binding, PMN310 may also lower the risk of the ARIA adverse events that have been reported associated with plaque-binding antibodies and allow for higher doses to treat the dementia. This premise is supported by preclinical toxicology studies in which weekly dosing of a murine IgG2a version of PMN310 in plaque-bearing knock-in APP^{SAA} mice at 800 mg/kg for 26 weeks did not cause brain hemorrhages (ARIA-H) upon microscopic examination using Perls' Prussian Blue staining to detect the presence of hemosiderin (*Kaplan et al, 2025, Alzheimer's Dement. 2025,* http://dx.doi.org/10.1002/trc2.70184).

The Company has conducted a toxicology study following Good Laboratory Practice (GLP) guidelines in cynomolgus monkeys. PMN310 was administered as a 30-minute intravenous (IV) infusion, on a weekly basis (Days 1, 8, 15, 22, and 29), at dose levels of 0, 200, 500, and 1,200 mg/kg/day. Administration of PMN310 was not associated with any adverse effects on clinical observations (local or systemic), body weight, food consumption, ECG, or hematology, coagulation, or urinalysis endpoints. No organ weight effects, macroscopic observations, or microscopic observations were attributed to PMN310 treatment at any doses. PMN310-related changes in clinical chemistry parameters were limited to mildly to moderately increased globulins (1.31x-2.00x) at 1200 mg/kg on Days 2 and 30 likely resulting from circulating PMN310 given one day prior. Based on the results of this study, the PMN310 NOAEL was considered to be 1,200 mg/kg/day in nonhuman primates when administered as a weekly 30-minute IV infusion over four weeks, which is five times higher than the comparable dose in humans that will be used in our Phase 1 trials.

Clinical Development Plan

The Company successfully manufactured PMN310 clinical supply under cGMP conditions and received clearance on its Investigational New Drug (IND) application with the FDA in May 2023 to initiate a Phase 1a clinical trial of PMN310. The Phase 1a trial was initiated in November 2023 as a placebo-controlled single ascending dose (SAD) trial in healthy volunteers testing single intravenous doses of PMN310 escalating from 2.5 to 40 mg/kg in 2-fold increments (NCT06105528). Each dosing cohort consisted of 6 drug-treated and 2 placebo-treated subjects. Results from all cohorts were presented at the Clinical Trials on Alzheimer's Disease Alzheimer Congress in October 2024. PMN310 was well-tolerated and there were no adverse events that precluded dose escalation. PMN310 crossed the blood brain barrier in a dose dependent manner with kinetics suggesting that monthly dosing can provide levels of PMN310 adequate for target engagement. The results informed dose selection for the Phase 1b, multiple ascending dose (MAD) study in patients with mild cognitive impairment due to AD or early AD.

Initiation of the Phase 1b PRECISE-AD trial (NCT06750432) commenced in December 2024 and was announced in early January 2025. In July 2025, PMN310 was granted Fast Track designation by the FDA. The ongoing PRECISE-AD

trial is a randomized, double-blind, placebo-controlled, MAD study of PMN310 to evaluate safety, tolerability, pharmacokinetics (PK), pharmacodynamics, and preliminary efficacy of multiple intravenous infusions of PMN310 in patients with early Alzheimer's disease. The study will also evaluate key biomarkers and clinical measures of efficacy to gather data on PMN310's therapeutic potential. Enrollment in the PRECISE-AD study was completed in December 2025 with 144 subjects enrolled across 21 active sites in the United States. The subjects are dosed monthly at one of three dose levels (5, 10, 20 mg/kg) or placebo over 12 months with assessment of safety, tolerability, PK, and pharmacodynamic blood-and CSF-based biomarkers of treatment effect at baseline and every three months. Frequent MRI scans throughout the study are being conducted to monitor for any emergence of ARIA.

To date, PMN310 has demonstrated a generally favorable safety profile, with limited patient discontinuations and no treatment-related serious adverse events (SAEs) reported during the trial. Based on current clinical trial patient visit schedules, the Company expects to complete the six-month assessments in the second quarter of 2026, with the blinded interim analysis anticipated in early third quarter 2026. Completion of all patient visits is expected in the fourth quarter of 2026, with top-line data anticipated in early 2027 following database lock and statistical analysis.

Safety will be a primary outcome with particular emphasis on assessing the expectation that, as a non-plaque binder, PMN310 will have a reduced risk of ARIA. The study is powered to provide 95% confidence for detection of ARIA. The study has been designed with a sample size intended to provide sufficient power to provide meaningful insight into effects of PMN310 on biomarkers and clinical outcomes. PRECISE-AD will be the first study to examine the effects of a monoclonal antibody directed solely against toxic Aβ oligomers on biomarkers associated with AD pathology and clinical outcomes.

Development of a Therapy for the Treatment of Amyotrophic Lateral Sclerosis

ALS Overview

Amyotrophic lateral sclerosis (ALS), commonly known as Lou Gehrig's Disease, is a progressive neurodegenerative disease that causes muscle weakness, paralysis and, ultimately, respiratory failure leading to death. ALS attacks randomly, and occurs throughout the world with no racial, ethnic or socioeconomic boundaries. It is estimated there are currently 30,000 people in the United States and 450,000 people worldwide, suffering from ALS, with approximately 5,000 new cases arising in the United States annually. Patients with ALS present symptoms such as progressive weakness, muscle atrophy and spasticity. These neurodegenerative and neuromuscular symptoms arise due to the ultimate degeneration of motor neurons in the spinal cord, the brain stem and in the brain cortex. Incurable and usually fatal within five years, ALS gradually robs a patient of the ability to walk, talk and breathe. Currently, there is no confirmatory test for ALS and many people go undiagnosed at early phases of the disease. Approximately two-thirds of those afflicted by ALS are currently undergoing some form of symptomatic treatment. There are no therapies approved that halt or significantly slow progression.

The biological mechanisms that cause ALS are only partially understood. Misfolded, aggregated TDP-43 forming inside neurons has been implicated in the pathogenesis of ALS (as well as frontotemporal lobe dementia or FTLD, and limbic-predominant age-related TDP-43 encephalopathy or LATE) through direct toxicity, loss of function of normal TDP-43, induction of misfolding of other neuronal proteins, and prion-like, cell-to-cell propagation of disease.

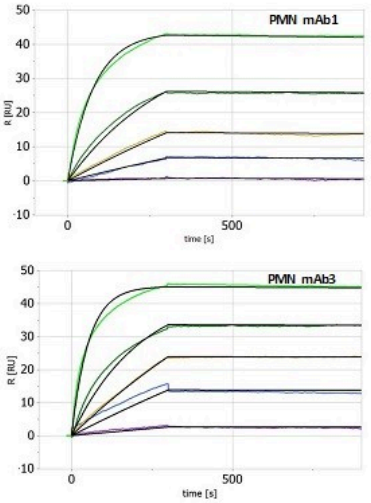
Experimentally, misfolded aggregates of TDP-43 are toxic to neural cells, and the prion-like propagation of TDP-43 aggregates has been demonstrated in cell culture and animal models. Importantly, misfolded TDP-43 has been found to induce the misfolding of other proteins into pathogenic aggregates (e.g., SOD1, nuclear pore proteins and transport proteins, DISC1), such that targeting misfolded TDP-43 potentially represents an opportunity to not only neutralize TDP-43 pathology but also interrupt this pathogenic interactome.

PMN267

Using the ProMIS discovery platform, we identified epitopes present on misfolded TDP-43 and generated high affinity antibodies (Fig. 4) that selectively recognized misfolded cytoplasmic aggregates of TDP-43 with no detectable interaction with normal TDP-43. Normal TDP-43 is located in the nucleus and is important for normal cell function (Fig. 5). The

antibodies recognized and stained pathogenic TDP-43 aggregates in spinal cord sections from ALS patients and brain sections from FTLD patients (immunohistochemistry) indicating that they have the potential to target disease-causing TDP-43. *In vitro* data showed that such antibodies can inhibit the cell-to-cell transmission of misfolded TDP-43 in the extracellular space thereby offering the potential to inhibit spreading of pathology (Fig. 6).

Figure 4



mAb	k_{ON} ($M^{-1}s^{-1}$)	k_{OFF} (s^{-1})	K_D (M)
PMN mAb1	4.03E+05	2.50E-05	6.20E-11
PMN mAb2	4.70E+05	4.32E-05	9.19E-11
PMN mAb3	5.99E+05	9.04E-06	1.51E-11

Fig. 4. High affinity mAbs. In Surface Plasmon Resonance (SPR) studies, serial dilutions of test mAbs were flowed over the target epitope immobilized on sensorchips to assess the binding kinetics and affinity. Binding curves were fitted to a Langmuir 1:1 interaction model.

Figure 5

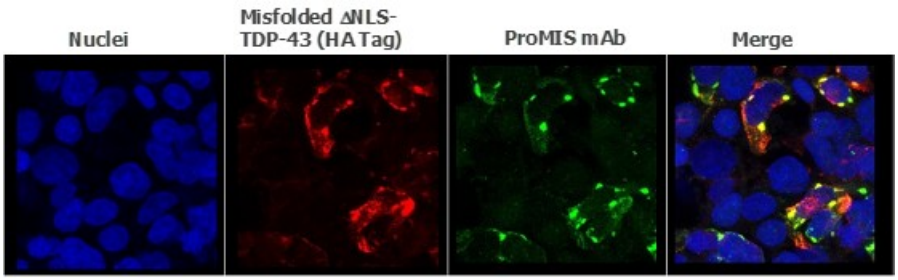


Fig. 5. Selective binding of mAb to misfolded, cytoplasmic aggregates of TDP-43. Staining of HEK293 cells transfected with mutant TDP-43 shows cytoplasmic aggregates of misfolded TDP-43 (red). Staining of the same cells with a PMN mAb (green) shows co-localization with TDP-43 aggregates with no staining of endogenous, normal TDP-43 in the nucleus (nuclei stained blue).

Figure 6

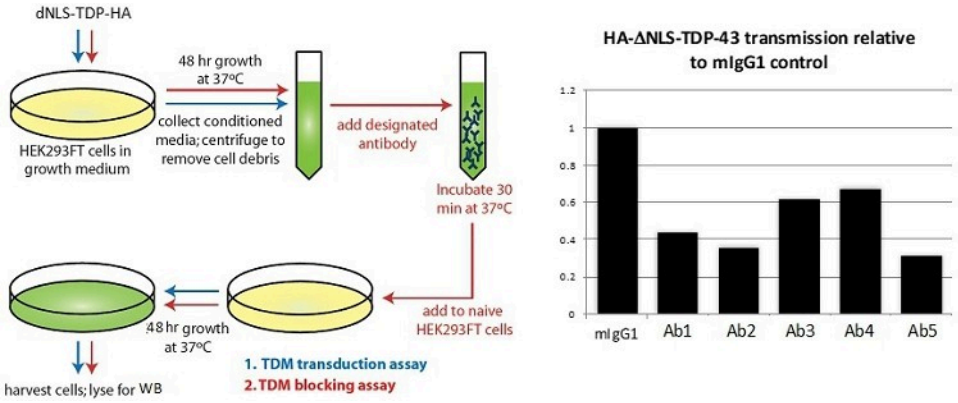


Fig. 6. Inhibition of cell-to-cell transmission of misfolded TDP-43 by mAbs. Supernatant from HEK293 cells transfected with misfolding mutant TDP-43 was incubated with test antibodies and added to naïve recipient cells to assess transmission of misfolding TDP-43 (HA-tagged). Compared to a mouse IgG1 negative control (mIgG1), several mAbs inhibited transmission to recipient cells as determined by a reduction in the density of the HA band on a Western blot of recipient cell lysate.

A complementary approach is to target intracellular TDP-43 to reduce toxic gains-of-function within the cell by generating intrabody versions of the TDP-43 antibodies. Intrabodies (from intracellular and antibody) are expressed from within the cell and were designed to target intracellular aggregates of TDP-43. Testing indicated that intrabodies expressed inside HEK293 cells associated selectively with pathogenic aggregates of TDP-43 in the cytoplasm (Fig. 7) and promoted degradation of the aggregates without affecting normal TDP-43 function or harming the cells (Fig. 8).

Figure 7

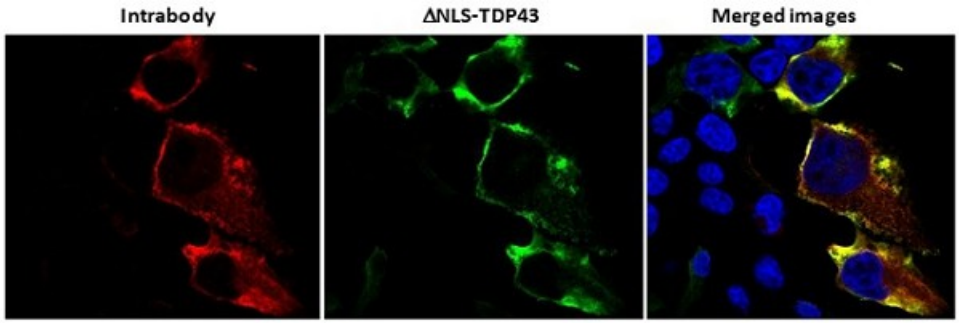


Fig. 7. Co-localization of intrabody with misfolded, cytoplasmic aggregates of TDP-43. Staining of HEK293 cells co-transfected with mutant TDP-43 (green) and plasmid encoding a PMN intrabody (red) shows co-localization of the two. There was no interaction of the intrabody with endogenous, normal TDP-43 in the nucleus (nuclei stained blue).

Figure 8

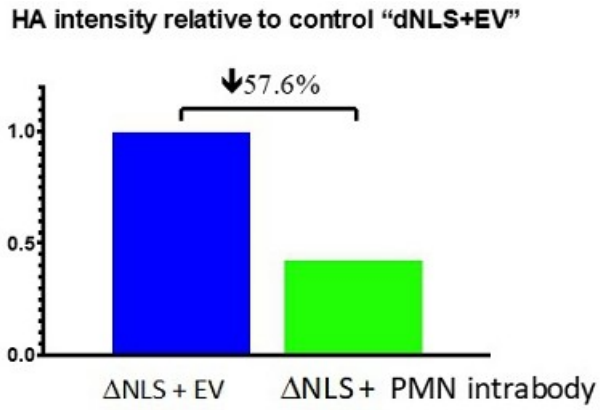


Fig. 8. Clearance of TDP-43 aggregates by intrabody. Transfection of HEK293 cells with a ProMIS intrabody results in degradation of HA-tagged mutant TDP-43 (dNLS) aggregates as measured by reduction in the density of the HA band on a Western blot of cell lysate compared to an empty vector (EV) control.

These results support the potential for using a mAb to selectively target and protect against pathogenic TDP-43. We believe an extracellular antibody could be used to interfere with the cell-to-cell spread of misfolded aggregates of TDP-43 in the extracellular space and slow disease progression. An intrabody construct delivered inside the cells via viral vectors used alone or in combination could be used to degrade intracellular aggregates and prevent further propagation.

The mAbs for TDP-43 generated using the ProMIS platform were tested for selective reactivity with misfolded TDP-43 aggregates and protective activity. Screening of multiple mAbs yielded PMN267 as the lead candidate exhibiting the desired properties. PMN267 bound its target epitope with high affinity in the 10E-11M range. In a cell system, PMN267 showed selective recognition of misfolded, cytoplasmic TDP-43 aggregates and no detectable interaction with endogenous normal TDP-43 in the nucleus. Similarly, PMN267 did not react with TDP-43 in stress granules, which are important in protection against oxidative stress. PMN267 also showed binding to exosomes derived from the brains of deceased FTLD individuals. Systemic IP delivery of PMN267 was tested in a transgenic mouse model of ALS/FTLD. In this model, doxycycline-regulated expression of human ΔNLS-TDP-43 is under control of the neurofilament heavy chain promoter such that progression of disease is driven by intracellular expression of aggregating ΔNLS-TDP-43 in all neurons, with little or no contribution of cell-to-cell spread of aggregates. In this aggressive model, a trend for improvement was observed with PMN267 treatment (30 mg/kg/week for 9 weeks) in the majority of motor function read-outs evaluated, including hind limb clasping, hind limb paralysis, grill test of agility, paw coordination, and footfall pattern. We believe the results suggest evidence of protection against motor function deficits by systemic, extracellular delivery of PMN267.

An intrabody version of PMN267 (single chain antibody sequence encoded into a plasmid) expressed from within cells showed co-localization with cytoplasmic aggregates of TDP-43 and no detectable binding to normal, nuclear TDP-43. Expression of the intrabody promoted degradation of misfolded TDP-43 aggregates in the HEK293 cell system by approximately 58% (Fig. 7). *In vitro* studies were also performed in collaboration with Dr. Gene Yeo at University of California, San Diego using iPSC-derived motor neurons from ALS patients, the cell type predominantly affected in ALS. In these studies, neurons transduced with vectorized PMN267 intrabody or a control protein (luciferase) were subjected to prolonged stress by puromycin-induced suppression of protein synthesis for 24 hours, giving rise to TDP-43 aggregates that persisted after another 24 hours of recovery. Neurons expressing PMN267 intrabody compared to control protein showed a 30-60% reduction in the amount of stress-induced TDP-43 aggregates as quantitated by high-content imaging. The Company believes that the observed selectivity of PMN267 for misfolded TDP-43 and avoidance of normal TDP-43 has the potential to allow for inhibition of disease without compromising essential TDP-43 function. PMN267 has been

humanized in a human IgG1 framework for IND-enabling studies to support the systemic, extracellular administration form. Development of the intrabody form would involve collaboration with a partner with expertise in viral vectorization.

Development of a Therapy for synucleinopathies

Overview

Strong genetic and experimental evidence supports a causative role for alpha-synuclein (a-syn) in the pathogenesis of several progressive neurodegenerative disorders known collectively as synucleinopathies, including Parkinson's disease (PD), dementia with Lewy bodies (DLB) and multiple system atrophy (MSA) (*Brundin et al, 2017, Exp Neurol; Lashuel et al, 2013, Nat Rev Neurosci*). Current evidence indicates that a-syn pathogenicity resides primarily with soluble, misfolded aggregates of the protein. In particular, oligomers and small soluble fibrils/protofibrils of a-syn have been reported to mediate neurotoxicity and progression of disease (*Fusco et al, 2017, Science; Bengoa-Vergniory et al, 2017, Acta Neuropathol)*. In contrast, a-syn monomers and insoluble fibrils appear to carry little or no direct toxicity (*Fusco et al, 2017, Science)*. Lewy bodies and Lewy neurites containing insoluble fibrillar deposits of a-syn are characteristic of disease but have actually been proposed to serve a protective role by sequestering toxic, misfolded aggregates of a-syn away from the cellular machinery (*Bengoa-Vergniory et al, 2017, Acta Neuropathol)*. Selective targeting of pathogenic forms of a-syn with antibodies represents an attractive therapeutic strategy. The advantage of selective antibodies, as opposed to a pan a-syn targeting approach, lies in preserving normal a-syn function and minimizing the diversion of active antibody from the target by non-toxic forms of the protein. By avoiding binding to abundant a-syn monomers in the blood and brain interstitial fluid, selective antibodies have the potential to achieve greater therapeutic effectiveness and reduce the risk of infusion reactions. Our candidate antibody targeting misfolded a-syn has the potential to be used across synucleinopathies sharing the same basic a-syn-driven pathogenesis.

PD is a progressive neurodegenerative disorder characterized by the loss of dopaminergic neurons located in the midbrain and the presence of intraneuronal inclusions (Lewy bodies/Lewy neurites) consisting mainly of aggregates of a-syn. Typical disease symptoms include tremors, rigidity, bradykinesia and postural instability. The average age of onset is typically early to mid 60's and it is estimated that over 1.1 million people in the U.S. and over 8.5 million worldwide are affected by the disease (*parkinson.org/understanding-parkinsons/statistics*). There is no cure for PD but several drugs are used to mitigate motor symptoms including dopamine, dopamine agonists, drugs that inhibit dopamine break-down and anticholinergics. While initially effective, symptoms can reappear as disease progresses. Deep brain stimulation using an electrode surgically implanted into brain tissue is also approved to treat dyskinesia, typically in patients who initially respond to dopamine treatment but develop symptoms despite drug therapy.

DLB is a progressive neurodegenerative disease characterized by deposits of insoluble a-syn fibrils (Lewy bodies, Lewy neurites) in the brainstem, limbic system and cerebral cortex leading to cognitive deficits, visual hallucinations and movement disorders. DLB affects approximately 1.0-1.4 million people in the U.S. with symptoms typically manifesting after age 50 (*medlineplus.gov/genetics/condition/dementia-with-lewy-bodies*). There is no cure and life expectancy is typically 5-8 years after diagnosis. Treatment is limited to managing symptoms including cholinesterase inhibitors to improve cognition, dopamine for motor symptoms and antipsychotics in some cases.MSA is a rare neurodegenerative disease with an estimated prevalence of 3.4 – 4.9 cases per 100,000 population. MSA is characterized by rapidly progressive autonomic failure and motor symptoms with predominant parkinsonian features (MSA-P) or dominant cerebellar features (MSA-C). There is no effective treatment and the mean survival from the onset of symptoms is 6 – 10 years. Histologically, the disease is characterized by a-syn aggregates in the cytoplasm of oligodendrocytes and, to a lesser extent, in neurons and other glial cells. A-syn aggregates from MSA brain homogenates have been demonstrated to cause MSA-like neurodegeneration in mice. The characteristics of MSA, although devastating for the patients, present several advantages for clinical development: disease progression is rapid allowing for earlier detection of therapeutic potential; high levels of neurofilament light chain (NfL) in serum represent a potential biomarker for inhibition of neuronal damage; and no placebo effects have been observed in clinical trials to date. Even though MSA is a rare disease, recruitment for clinical trials of other candidates has been facilitated by the unmet need and existence of a global MSA Registry (GLOMAR), along with supporting organizations.

There is an urgent unmet medical need for the development of therapies against synucleinopathies. Selective targeting of pathogenic a-syn species with our candidate has the potential to provide a clinical benefit where no satisfactory safe and effective options currently exist.

PMN442

Multiple studies indicate that pathogenic aggregates of a-syn can propagate from cell-to-cell in a prion-like manner causing progressive neuronal damage and disease symptoms. Using the ProMIS platform, several conformational epitopes were identified as likely to become exposed on misfolded, pathogenic forms of a-syn (toxic oligomers and soluble seeding fibrils). MAbs were raised against these epitopes and were tested for the desired binding profile and ability to protect neurons against toxic a-syn species *in vitro*. Traditional methods are unable to generate antibodies with adequate precision to selectively target these neurotoxic forms of a-syn. ProMIS used its proprietary technology platform for generating and developing antibodies that can uniquely and precisely target these specific toxic forms. As illustrated in figure 9, ProMIS mAbs showed the ability to selectively bind the pathogenic forms of a-syn (toxic oligomers and small soluble fibrils) but not a-syn monomers that play an important functional role in the brain.

Figure 9

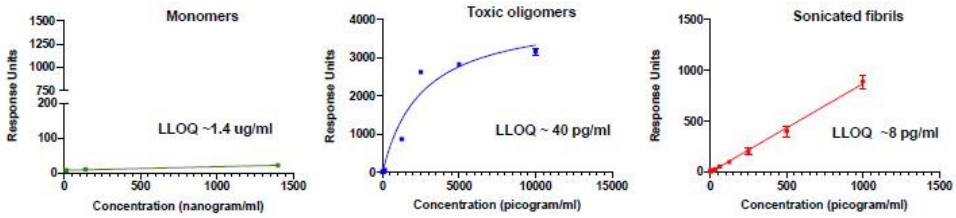


Fig. 9. Selectivity of mAbs for pathogenic species of a-syn. The binding response of a representative mAb to various concentrations of a-syn monomers, toxic oligomers and soluble fibrils (sonicated PFFs) measured in a Millipore immunoassay. Mean ± SD of triplicates shown with the calculated lower limit of quantitation (LLOQ) for each species.

Multiple mAbs were screened and PMN442 emerged as the lead candidate and PMN411 as a back-up with the desired characteristics for this program. As measured by surface plasmon resonance (SPR), PMN442 showed robust binding to toxic a-syn oligomers and seeding fibrils, with negligible binding to a-syn monomers and physiologic tetramers which are required for normal neuronal function (Figure 10). PMN442 also reacted with native toxic a-syn present in brain homogenates from individuals with MSA and DLB (Figure 11).

Figure 10

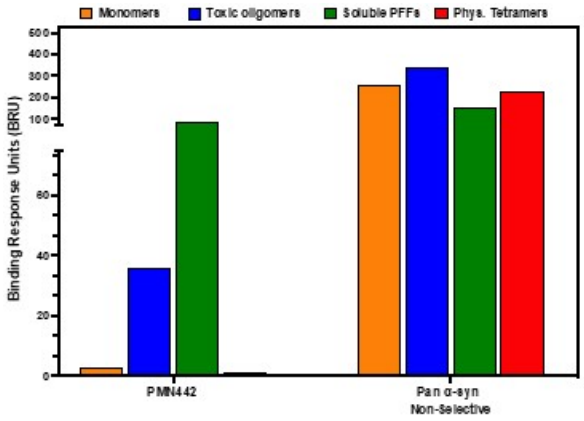


Fig. 10. Selective binding of PMN442 to pathogenic species of a-syn by SPR. The binding response of immobilized PMN442 to a-syn monomers, toxic oligomers, soluble (seeding) preformed fibrils (PFFs) and physiologic (Phys.) tetramers was measured by SPR. The same pattern of binding was observed in 4 independent experiments.

Figure 11

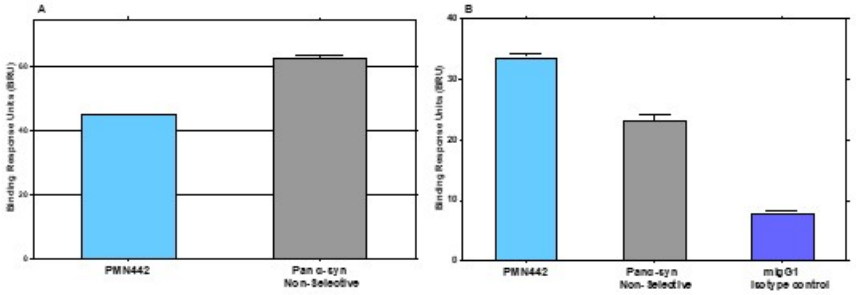


Fig. 11. Binding to native pathogenic a-syn species in patient brain extract. The binding response of immobilized PMN442 to a-syn in brain extract from dementia with Lewy bodies (DLB) (A) and MSA (B) patients was measured by SPR. A pan a-syn reactive antibody and mouse IgG1 (mIgG1) were used as controls. Results shown are the mean $\pm$ SEM of two (A) or four (B) independent studies.

In activity assays, PMN442 protected rat dopaminergic neurons against neuronal death by a-syn toxic oligomers (Figure 12). In separate assays, PMN442 also inhibited the processes involved in the cell-to-cell propagation of a-syn aggregates: it reduced the uptake of human a-syn seeding fibrils by neurons and the subsequent formation of intracellular aggregates, as well as the recruitment of endogenous normal a-syn into those aggregates (Figure 13). Taken together, these results support the potential of PMN442 to selectively target and protect against a-syn pathogenic species in patients with MSA and other synucleinopathies. PMN442 has been humanized in a human IgG1 framework for advancement to IND-enabling studies.

Figure 12

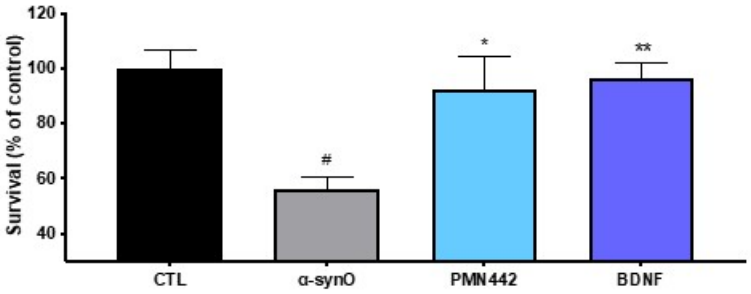


Fig. 12. Protection against neurotoxicity. PMN442 inhibition of oligomer toxicity for dopaminergic neurons. Cultures of primary rat dopaminergic neurons were exposed to toxic a-syn oligomers with or without PMN442. Survival is expressed as the percentage of viable neurons compared to a control culture with vehicle only (CTL). Results shown are the mean ± SEM of 6 replicate cultures. BDNF was used as a positive control. # $p = 0.0004$ vs. CTL, *$p \leq 0.002$ vs. a-synO, **$p \leq 0.003$ vs. a-synO.

Figure 13

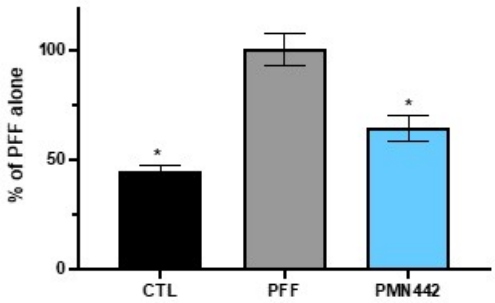


Fig. 13. Inhibition of seeding activity. PMN442 inhibition of the recruitment of endogenous rat a-syn into phosphorylated aggregates. Cultures of primary rat hippocampal neurons were exposed to soluble human a-syn preformed fibrils (PFF) with or without PMN442. CTL = neurons incubated with vehicle alone. Results are expressed as a percentage of the phosphorylated rat a-syn staining area with PFF alone and show the mean ± SEM of 6 replicate cultures. *$p<0.02$ vs PFF.

DEVELOPMENT PROGRAMS

Expansion to Include Other Neurodegenerative and Misfolded Protein Diseases

The ProMIS discovery platform is being applied to other toxic misfolded proteins that drive disease including DISC1 in schizophrenia, and RACK1 in ALS in order to potentially generate antibody therapies for these disorders. Under disease conditions, misfolding of each of these proteins leads to the formation of toxic aggregates inside brain cells that can spread damage by propagating from cell-to-cell. Disease-associated conformational epitopes identified through ProMIS' computational platform are being used to generate potentially therapeutic antibodies. Additionally, we are using the epitopes identified in the amyloid-beta, alpha-synuclein and TDP-43 discovery programs to generate vaccine candidates that potentially could be used for prophylactic treatment of Alzheimer's disease, synucleinopathies and ALS, respectively. The Discovery phase of the process comprises two distinct stages: (1) computational modeling to predict and construct

conformational peptide epitopes present on the misfolded, toxic form of a protein, followed by either immunization with the peptide epitopes to generate antibodies/ intrabodies, or incorporation of the peptide antigen into a therapeutic vaccine and (2) screening and validation of multiple candidates in vitro and in vivo to select a lead for preclinical development.

Alzheimer's disease

Schizophrenia

DISC1

Protein misfolding and proteostasis defects have been found to play a role in neurodevelopmental diseases, but until recently, the proteins implicated in these disease processes were not known. Just such a protein was first identified in a Scottish family with an autosomal dominant neurodevelopmental syndrome including schizophrenia, and was subsequently named "disrupted in schizophrenia," or DISC1 (Soares et al. 2011). DISC1 is an important hub protein participating in neurogenesis, mitochondrial transport and dynamics in dendrites, cytoskeletal function, and protein translation in adults, especially at the synapse and under conditions of oxidative stress. DISC1 has been shown to misfold and aggregate in schizophrenia, as indicated by impaired detergent solubility in brains of individuals dying with sporadic (non-genetic) schizophrenia (Leliveld et al. 2008), and the induced co-aggregation of DISC1 by TDP-43 inclusions in human frontotemporal dementia (Endo et al. 2018). In addition, many genetic variants in interactors of DISC1 show significant association with schizophrenia and cognitive decline. Finally, misfolded DISC1 has been shown to exhibit prion-like attributes with transmission from cell-to-cell that can trigger misfolding of healthy DISC1 in the recipient cell (Korth 2012). Thus, DISC1 can be designated a misfolding protein in schizophrenia, just like amyloid and tau are misfolded proteins in AD. We believe application of the ProMIS platform to DISC1 and its interactome offers the potential to generate selective antibodies to selectively degrade toxic misfolded DISC1 while sparing normally folded DISC1 to perform its physiological function. Immunizations have been performed with epitopes predicted by EpiSelect™ to be present specifically on misfolded DISC1 and the resulting mAbs are being characterized.

Amyotrophic Lateral Sclerosis

RACK1

RACK1 is a core ribosomal protein of the eukaryotic small (40S) ribosomal subunit. It is a scaffold protein that interacts with several other proteins thereby regulating a variety of signaling pathways critical for cell proliferation, transcription and protein synthesis. It is essential for proper neuronal function. In ALS, our own findings and those of others indicate that misfolded RACK1 co-localizes into cytoplasmic aggregates in motor neurons of the spinal cord which may play a role in disease pathology. For example, in a cell system, we and others have found that mutant TDP-43 suppresses global protein synthesis by co-aggregating with RACK1 on polyribosomes. Our recent work indicates that the same observations also apply to the interaction between RACK1 and Fused in sarcoma/translocated in sarcoma (FUS), another protein associated with ALS pathogenesis.

To investigate RACK1 as a potential target for ALS, ProMIS explored the impact of RACK1 knock-down (KD) (i.e., what happens in the absence of RACK1). Our findings were recently published in *Acta Neuropathologica Communications* (https://doi.org/10.1186/s40478-023-01705-8). In a cell system, RACK1 was observed to co-aggregate with misfolded mutant TDP-43 or mutant FUS in the cytoplasm. Knock-down of RACK1 expression resulted in disaggregation of cytoplasmic TDP-43 or FUS and even relocation to the nucleus (normal location) in some of the cells, accompanied by a reversal of the suppression of protein synthesis. In fruit flies (*Drosophila melanogaster*) experiencing neurodegeneration as a result of human TDP-43 expression, RACK1 KD alleviated degeneration of neurons in the retina and improved the climbing ability of the flies.

Results from the literature and ProMIS' proof of concept data using RACK1 KD support targeting of RACK1 as a potential therapeutic approach for ALS. The ProMIS platform identified epitopes present on misfolded RACK1 and generated antibodies selective for pathogenic, aggregated RACK1.

ProMIS has generated five mAbs with the desired selectivity and intrabody versions have been generated for testing. These mAbs recognize diseased tissue (ALS and FTD) but not normal tissue, suggesting that RACK1 is misfolded and aggregated in disease. Research is ongoing to continue to characterize the mAbs and select a candidate. Selective KD of RACK1 is another avenue being pursued.

Alzheimer's Vaccine Program

We believe that the same peptide antigens that generate a mAb infusion therapy can be used to create a vaccine. The goal of a therapeutic vaccine is to spur the human immune system to generate antibodies that neutralize toxic oligomers, just as the infusion antibodies will hopefully do. The advantage is that a single course of therapy, usually an initial vaccination followed by a booster, can potentially provide years of therapeutic benefit, eliminating the need for frequent costly infusions. Progress in the reliability of blood-based biomarkers of neurodegeneration will likely increase screening to identify individuals in the early stages of AD or at risk of developing the disease. A vaccine capable of inducing an effective antibody response against AβO could be administered prophylactically to at-risk individuals to potentially prevent development of symptomatic disease; and the vaccine could also be given therapeutically to individuals living with a diagnosis of AD to potentially inhibit disease progression. Initial results obtained with peptide 301 (the conformational AβO epitope of PMN310) in a vaccine configuration showed robust induction of antibodies selective for AβO with no binding to monomers or plaque. There was also no induction of a potentially deleterious T cell response observed previously with other Ab vaccines. ProMIS performed studies to optimize adjuvant formulation and dosing regimen as well as to explore multivalent vaccine configurations containing additional AbO-restricted epitopes identified by the ProMIS discovery platform. Results from these studies showed that maximal reactivity with toxic oligomers from AD brain was achieved with immune IgG against conformational epitope 301 alone and that there was no advantage of including additional epitopes in the vaccine. These data were presented at the 2024 Alzheimer's Association International Conference.

In previous studies reported in the literature, a first-generation vaccine consisting of aggregated human Aβ protein with QS1 adjuvant induced antibody production in AD patients but elicited meningoencephalitis (brain inflammation) and had to be discontinued for safety reasons. Subsequent studies indicated that T helper (Th) cell epitopes in the Aβ vaccine gave rise to a pro-inflammatory Th1-type response against the same Aβ epitopes in the brain*)*. The Company believes it can avoid this issue with a vaccine candidate consisting of its AβO B cell epitope (no Aβ Th epitopes) conjugated to keyhole limpet hemocyanin (KLH) as a carrier protein. KLH has been used in humans and provides Th cell epitopes that are needed to help the development of an antibody response by B cells. Since KLH is a foreign protein not present in human brain, immunization is expected to result in an antibody response against AβO without a potentially detrimental Th cell inflammatory response (Fig. 14). This premise is supported by initial preclinical studies that we conducted in collaboration with the University of Saskatchewan's Vaccine and Infectious Disease Organization-International Vaccine Centre (VIDO-InterVac), a global leader in vaccine research and development. The results were first presented at the AD/PD conference in 2022.

In these studies, 5-6 week old Balb/c mice (n=6/group) received two intramuscular (IM) injections (days 0 and 28) of a vaccine candidate construct containing ProMIS' AβO 301 peptide epitope linked to KLH and formulated with different adjuvants. Analysis of serum samples collected on day 0 and after 1 or 2 vaccinations on days 28 and 48 showed induction of a robust antibody response against the AβO epitope as measured by ELISA (Fig. 15). ELISPOT analysis of spleen cells (immune cells) collected from immunized mice at the end of the study on day 48 showed a lack of Th cell cytokine production in response to stimulation with the AβO epitope thereby indicating that the peptide only contains a B cell epitope. As expected, T cell help was provided by the carrier protein and stimulation with KLH gave rise to the production of Th cytokines. These results support the premise that a vaccine consisting of AβO-restricted conformational B cell epitopes conjugated to KLH for T cell help may successfully induce a protective antibody response against AβO without eliciting a potentially inflammatory Aβ-directed Th response. Characterization of immune sera from the mice also showed the desired antibody binding profile: selective binding to AβO compared to Aβ monomers as determined by SPR, and no binding to plaque in brain sections from AD patients as determined by IHC.

Figure 14

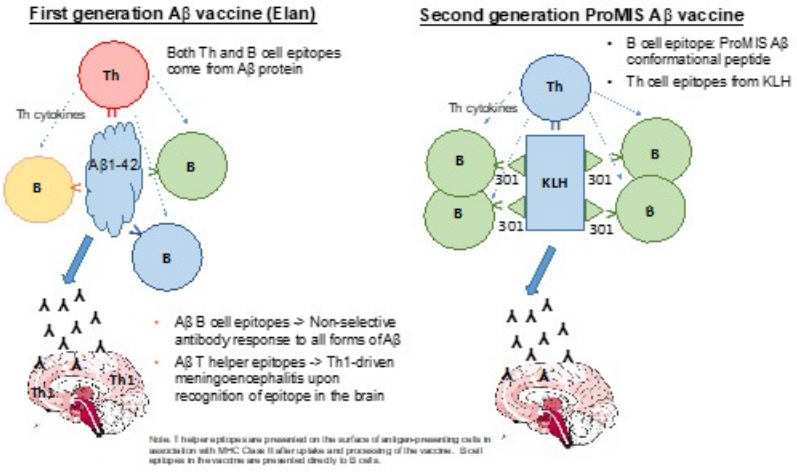


Fig. 14. Illustration of vaccine concept

Figure 15

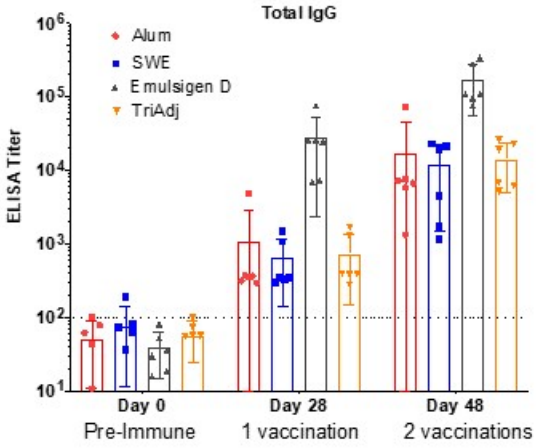


Fig. 15. Induction of robust antibody response against AβO epitope. Titers of IgG antibodies against the 301 peptide epitope were measured by ELISA. Values for individual mice at baseline and on days 28 and 48 post-immunization are shown.

Using the ProMIS discovery platform, our aim is to devise a safe and effective vaccine to induce a specific immune response against toxic AβOs. We have identified a lead candidate vaccine to induce antibodies that selectively bind AβOs. The immediate goal for this program is to progress this amyloid vaccine into preclinical development.

Alpha-Synuclein & TDP-43 Vaccine Program

The same principle of immunization with conformational peptide epitopes of misfolded toxic proteins was applied to alpha-synuclein (a-syn) for vaccination against synucleinopathies such as MSA, PD and LBD. Potential conformational epitopes (misfolded portions) unique to toxic alpha-synuclein were identified by the ProMIS platform. Formulations of several of these epitopes were tested in mouse vaccination studies leading to the selection of a lead vaccine candidate for testing in mouse models replicating cognitive and motor deficits of human disease. This pioneering work was made possible through a C$1.16 million research grant by the Weston Family Foundation to the University of British Columbia to support the research of the team led by Neil Cashman, M.D., ProMIS Chief Scientific Officer and Professor Emeritus at the University of British Columbia. The team also includes Scott Napper, Ph.D., from the Vaccine and Infectious Disease Organization (VIDO) and Professor of Biochemistry, Microbiology, and Immunology at the University of Saskatchewan, Marco Prado, Ph.D., the Canada Research Chair in Neurochemistry of Dementia and Professor of Anatomy & Cell Biology / Physiology and Pharmacology, at the University of Western Ontario, and Joel Watts, Ph.D., Canada Research Chair in Protein Misfolding Disorders and Associate Professor within the Department of Biochemistry and the Tanz Centre for Research in Neurodegenerative Diseases at the University of Toronto.
Results from vaccination studies were presented at the 2025 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD) and at the American Academy of Neurology (AAN) conference.

Similarly, an epitope determined to be restricted to misfolded pathogenic TDP-43 was formulated as a vaccine. Results from a mouse vaccination study were accepted for presentation at the 2026 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD).

ProMIS' Technology Platform and Intellectual Property Portfolio

The basis of ProMIS' proprietary technology platform is the ability to identify small regions of toxic proteins, including their specific shape or "conformation" that are displayed only on the toxic forms of that protein. We have developed patented methods and know-how combining biology and physics, to identify these small regions of proteins which can be the targets for antibodies. When displayed on the toxic protein, these small regions are known as "epitopes." ProMIS makes copies of these epitopes, in a precisely defined shape. These drug development tools are called peptide antigens and we believe they are the key to our ability to create antibody therapies, vaccines, and diagnostics.

The ProMIS computational platform is based on the EpiSelect™ algorithm that combines physics and biology to simulate the folding, or misfolding of proteins. ProMIS has successfully applied this computational algorithm to several misfolded protein categories, looking for epitopes exposed only on a misfolded toxic form which can be used as an antigen to generate an antibody.

Peptide antigens are the key to creating selective antibodies that target toxic misfolded proteins, like our lead therapeutic antibody candidate (PMN310 for AD). PMN310 was created using a peptide antigen that we correctly predicted to be exposed only on toxic AβOs, not the monomeric or plaque forms of Aβ. ProMIS has generated a portfolio of over 20 peptide antigens that have led to selective antibodies against toxic misfolded forms of Aβ for AD, a-syn for MSA and PD, tau for AD, FTLD, PSP, and CBD, TDP-43 and SOD1 for ALS, RACK1 for ALS and HD, and DISC1 for schizophrenia. Those peptide antigens, and the corresponding selective antibodies, represent proprietary reagents that potentially can be used to create proprietary diagnostic tests in neurodegenerative diseases.

Finally, peptide antigens are also a potential key to making vaccines. Therapeutic vaccines are designed to treat a disease by causing the patient's immune system to make antibodies (or T-Cells, in some areas like cancer) that neutralize the toxic disease driver. The potential advantage of a therapeutic vaccine, if effective, is that a single course of therapy might provide benefit for many years, not requiring frequent, expensive and inconvenient infusions. In preventive therapy, we believe such an approach may be particularly valuable.

Overview of ProMIS' Intellectual Property (IP) Portfolio

The ProMIS IP program consists of a three-layered strategy. The first layer of protection comprises two computational algorithms, ProMIS™ and EpiSelect™, obtained under worldwide exclusive license from the UBC. These algorithms are

used to predict the specific site and shape (conformation) of epitopes on misfolded proteins implicated in the development of neurodegenerative diseases and on other complex proteins. PCT applications for these disease specific epitopes have been submitted and comprise the second layer of IP protection. Finally, the third layer of protection consists of the composition of matter for the antibodies targeting these disease related epitopes, including use(s) thereof. The second and third layers of this strategy may be in the same patent application.

License Agreements and Patents

License Agreement with the University of British Columbia (UBC)

On February 4, 2009, ProMIS (under its previous name, Amorfix Life Sciences Ltd.) entered into an exclusive license agreement with UBC in which ProMIS gained exclusive worldwide rights to develop and commercialize certain intellectual property rights belonging to UBC, based on its technology relating to misfolded proteins. Such agreement was amended and restated effective October 6, 2015 (as amended and restated, the "UBC License Agreement"). Under the terms of the UBC License Agreement, ProMIS has a worldwide exclusive license to UBC's rights in existing and future intellectual property (Improvements as defined in the UBC License Agreement) related to misfolded protein technology, with the right to sublicense. ProMIS is also responsible for managing the filing, maintenance and prosecution of the licensed patents and applications and is responsible for costs associated with the same. The UBC License Agreement expires on a product by product and country by country basis upon the expiration of ProMIS' obligation to pay royalties to UBC under the terms thereof (unless terminated earlier pursuant to the terms of the UBC License Agreement). The Company's obligation to pay royalties under the UBC License Agreement expires upon the longer of the life of the Patents (as defined in the UBC License Agreement), including those identified in Schedule A thereto (as amended from time to time), and ten years following the First Commercial Sale of a Product (as those terms are defined in the UBC License Agreement) in any country. Since the Company has not made commercial sales under the UBC License Agreement to date, the UBC License Agreement is currently expected to expire no earlier than February 19, 2044. However, this date may be adjusted upon the Company's First Commercial Sale of a Product or upon an amendment to Schedule A to the UBC License Agreement to add additional patents. The UBC License Agreement may also be terminated by UBC, at its option, upon the occurrence of certain events including, but not limited to, our insolvency, winding up, liquidation, if the subject technology becomes subject to a security interest that is not released, if ProMIS or any of its directors or officers have materially breached or failed to comply with securities laws, in the event of certain breaches of, or our failure to perform obligations under, the UBC License Agreement or other agreements between ProMIS and UBC or other terminations of existence. Either party may terminate the license for breaches pursuant to the terms thereof, unless remedied within a certain period specified in the UBC License Agreement. ProMIS also has the right, in its sole discretion, to terminate the UBC License Agreement upon written notice to UBC. The UBC License Agreement calls for certain customary payments such as an annual license fee and payment to UBC of a low to high single digit royalty on revenues. As of December 31, 2025, the Company has paid a total of C$275,000 to UBC pursuant to the terms of the UBC License Agreement.

The foregoing description of the UBC License Agreement is qualified in its entirety by reference to the UBC License Agreement.

The UBC Patents

The UBC patent license includes a patent family directed toward systems and methods for predicting therapeutic targets in misfolding proteins. This patent family (referred to as Collective Coordinates target identification technology) includes one issued U.S. patent, eight issued foreign patents and one allowed Canadian application. Issued patents from this family are expected to expire in November 2036, absent any disclaimers or extensions available.
The UBC patent license also includes several patent families directed to biologics including antibodies targeting neurological disease related toxic misfolded proteins and methods related thereto, many of which targets were identified using their proprietary prediction systems and methods, including several families related to immunogens, antibodies and methods directed to various misfolded Aβ targets relevant in AD and related diseases (AD family), several families related to immunogens, antibodies and methods directed to various misfolded TDP-43 targets relevant in ALS and related diseases (ALS disease family-TDP-43), a patent family related to antisense molecules and biologics directed at RACK1 relevant in ALS and Huntington's (ALS disease family-RACK1), a patent family related to ubiquitin ligase

fusions directed to misfolded SOD1 targets relevant in ALS and related diseases (ALS disease family – SOD1), a PCT patent application related to vaccine compositions, and a patent family related to immunogens and antibodies directed to a-synuclein targets relevant in PD, MSA, LBD and related diseases (PD family).

The AD family includes patent families related to three Aβ epitope targets. The first Aβ epitope target patent family includes several patent subfamilies and includes specifically four issued U.S. patents, three pending U.S. applications, nineteen issued foreign patents and seven foreign pending patent applications. Issued patents from this family are expected to expire in November 2036, July 2037 or July 2038, depending on the subfamily and country and absent any disclaimers or extensions available. The second Aβ epitope target patent family includes two issued U.S. patents, two issued foreign patents and five foreign pending applications. Issued patents from this family are expected to expire in November 2036, absent any disclaimers or extensions available. The third Aβ epitope target patent family includes two issued U.S. patents, three issued foreign patents and one foreign pending application. Issued patents from this family are expected to expire in November 2036, absent any disclaimers or extensions available. The AD family also includes one issued U.S. patent directed to combinations of the three Aβ epitope target antibodies and an issued U.S. patent directed to combinations of the three Aβ epitope target immunogens. Issued patents from this family are expected to expire in November 2036, absent any disclaimers or extensions available.

The ALS disease family-TDP-43 includes patent families directed to two TDP-43 epitope targets. The first TDP-43 epitope target family includes one issued U.S. patent, one pending U.S. application, one issued foreign patent, and two pending foreign applications. Issued patents from this family are expected to expire in May 2038, absent any disclaimers or extensions available. The second TDP-43 epitope target family includes two patent subfamilies, the earlier of which includes one allowed U.S. patent application, one pending U.S. patent application, and seven pending foreign applications, and a later patent subfamily directed more specifically to intrabodies, that includes one pending U.S. application and 5 foreign patent applications. Patents that issue from this family would be expected to expire in December 2039 and April 2041, respectively, absent any disclaimers or extensions available.

The ALS disease family- SOD1 includes a patent family related to a SOD1 epitope target. The patent family includes one pending U.S. application and eight pending foreign applications. Patents that issue from this family would be expected to expire in February 2044, absent any disclaimers or extensions available.

The ALS disease family also includes a patent family related to RACK1 nucleic acid targets. The RACK1 nucleic acid target family includes one pending U.S. patent application and five pending foreign applications. Patents that issue from this family are expected to expire April 2041, absent any disclaimers or extensions available.
The PD disease family includes a patent family related to alpha-synuclein epitope target. The a-syn patent family includes one issued U.S. patent, one pending U.S. patent application, two issued foreign patents, and four foreign pending patent applications. Issued patents from this family are expected to expire in October 2039, absent any disclaimers or extensions available. The PD disease family also includes a PCT application directed to vaccine compositions. Patents that issue from applications related to this PCT would be expected to expire in May 2045, absent any disclaimers or extensions available.

Other Patents

We are the current owner of two U.S. patents related to SOD1 epitope targets that were co-owned and then acquired from University Health Network (UHN) by assignment. These patents expire on March 2026 and December 2026, absent any disclaimers or further extensions available. We also own a U.S. patent related to SOD-1 immunogens and/or antibodies which is expected to expire March 2026. We also own one U.S. patent directed to detecting misfolded disease associated proteins. This patent is expected to expire in July 2034, absent any disclaimers or further extensions available.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In the countries in which we file, the patent term is 20 years from the earliest non-provisional filing date, subject to any disclaimers or extensions and to the timely payment of maintenance fees. The term of a patent in the United States can be adjusted due to any failure of the U.S. Patent Office (USPTO) following certain statutory deadlines for issuing a patent.

For a discussion of the risks we face relating to our intellectual property, see "*Risk Factors — Risks Related to our Intellectual Property — If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates, and other proprietary technologies if approved, may be adversely affected.*"

Industry Overview

Markets

ProMIS is applying its in-licensed patented technology platform to build a portfolio of antibody therapies and therapeutic vaccines, for neurodegenerative diseases such as AD, ALS, MSA, FTLD, PSP, CBD, and schizophrenia. A common biologic cause contributes to each of these conditions, in that misfolded versions of proteins which normally perform a needed function can cause neuronal degeneration and death when misfolded, contributing to morbidity and mortality. ProMIS' technology platform is an example of the advances in drug discovery enabled by computational power, in silico discovery, and artificial intelligence. We believe this platform provides a potential advantage by allowing us to selectively target the toxic misfolded proteins with therapeutics.

Marketing Plans and Milestones

Marketing and commercial launch of any products in the ProMIS portfolio which successfully progress in development must be planned in relation to its available resources. ProMIS intends to out-license the marketing and sales of its products, should they progress successfully in development, to strategic partners for commercialization.

Government Regulations

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture, testing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, as well as diagnostics. Generally, before a new drug, biologic or diagnostic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved, authorized, or cleared by the applicable regulatory authority.

Regulatory Approval and Certification

All commercial applications of ProMIS' technology will be subject to substantial regulation and certification in the jurisdictions in which ProMIS or its strategic partners intend to sell its therapeutic products. The initial markets for ProMIS' product candidates are expected to be the U.S. and Canada and, because the Canadian healthcare marketplace is regulated in a similar manner as in the United States, ProMIS intends to conform its regulatory and certification scheme to the more rigorous standards imposed by the FDA.

Human Therapeutic Products

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations and biologics under the FD&C Act and the Public Health Service Act (PHS Act) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires 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, approval process or following approval may subject an applicant to administrative actions or judicial

sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our product candidates, if approved, and our reputation.

Our product candidates must be approved by the FDA through either a New Drug Application (NDA) or a Biologics License Application (BLA) process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practices (GLP) requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board (IRB) or independent ethics committee (EC) at each clinical trial site before each human trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices (GCP) requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with Current Good Manufacturing Practices (cGMP) requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and the regulatory scheme for drugs and biologics is evolving and subject to change at any time. We cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical and Clinical Development

ProMIS' human therapeutic product applications will be subject to rigorous preclinical and clinical testing and other approval procedures by the FDA and similar regulatory agencies in other countries. First, preclinical testing of human therapeutics is conducted in nonclinical models and on animals in the laboratory to evaluate the potential efficacy, safety and toxicity of a pharmaceutical product candidate. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

The results of these studies, along with applicable chemistry, manufacturing, and controls information are submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to

humans, and must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Additionally, the review of information in an IND submission may prompt FDA to, among other things, scrutinize existing INDs or any marketed products and could generate requests for information or clinical holds on other product candidates or programs.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. The FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

Typically, the clinical evaluation process involves three phases. In Phase 1, clinical trials are conducted with a small number of healthy human subjects, or in a small number of patients to determine the early safety profile, the pattern of therapeutic drug distribution and metabolism. The total number of subjects included in Phase 1 clinical trials varies but is generally in the range of 20 to 80. In Phase 2, clinical trials are conducted with groups of patients who have the disease being evaluated to determine preliminary evidence of efficacy, the optimal dosages, and more extensive evidence of safety. Phase 2 clinical trials are typically controlled and conducted in a limited population, usually involving no more than several hundred subjects. In Phase 3, large scale, statistically-driven multi-center, well-controlled clinical trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA. Phase 3 clinical trials usually involve several hundred to several thousand subjects. In most, though not all, cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to support approval of a drug.

Data from clinical trials conducted outside the U.S. may be accepted by the FDA subject to certain conditions. For example, the clinical trial must be conducted in accordance with GCP) requirements and/or the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U.S. patient population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The

sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as 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 and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA or BLA, for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA or BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision.

The FDA conducts a preliminary review of all NDAs or BLAs 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 or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA or BLA to determine, among other things, whether the drug or biologic is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality, and purity.

The FDA may refer an application for a novel drug or biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which 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 or BLA, the FDA typically will 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 requirements and adequate to ensure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or BLA and may require additional clinical or

preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's or biologic's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a Risk Evaluation and Mitigation Strategy (REMS) which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or 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 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same approved use or indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same approved use or indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity.

Expedited Development and Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs or biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to expedite the development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

A drug may be eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application. In addition, a drug may

be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

A product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review designation, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they are in development for a serious or life-threatening condition and can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which 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.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product, other evidence demonstrates that the product is not shown to be safe and effective under conditions of use, or required post-approval studies are not conducted with due diligence. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted Accelerated Approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

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 the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (PREA), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act (FDASIA) amended the FD&C Act to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration, unless the drug is for an indication for which orphan designation has been granted and is not for a molecularly targeted cancer indication, submit an initial Pediatric Study Plan (PSP) within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of

the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and, for drugs, patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or, for drugs, patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Post-approval Requirements

Drugs or biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with 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 user fee requirements for any marketed products and the establishments where such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or biologics may be promoted only for the approved indications 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, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with ongoing regulatory requirements, including cGMP requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution.

Once an approval of a drug or biologic is granted, the FDA may withdraw the 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 mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution 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;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs or mandated modification of promotional materials and labeling and issuance of corrective information.

In many foreign countries, drugs and biologics are subject to regulatory requirements in addition to and sometimes different than the U.S. requirements described herein.

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

Companion Diagnostics

The FDA defines an *in vitro* companion diagnostic (IVD) device as an *in vitro* diagnostic device that provides essential information for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, including the label. Applications for an IVD companion diagnostic device and its corresponding therapeutic product will be reviewed and approved according to applicable regulatory requirements. The IVD companion diagnostic device application will be reviewed and approved or cleared under the device authorities of the FD&C Act and relevant medical device regulations; the therapeutic product application will be reviewed and approved under section 505 of the FD&C Act (i.e., drug products) or section 351 of the Public Health Service Act (i.e., biological products) and relevant drug and biological product regulations. The FDA intends to review each IVD companion diagnostic device submission within the context of, or in conjunction with, its corresponding therapeutic product, and FDA review of the IVD companion diagnostic device and the therapeutic product will be carried out collaboratively among relevant FDA offices.

Ideally, a therapeutic product and its corresponding IVD companion diagnostic device should be developed contemporaneously, with the clinical performance and clinical significance of the IVD companion diagnostic device established using data from the clinical development program of the corresponding therapeutic product. Some of our current and future product development candidates may depend upon co-development of accurate genetic and potentially

other IVDs. Thus, we will likely need to comply with both FDA drug and medical device regulations. This adds additional cost and complexity to our development programs. Ultimately, FDA approval of a companion diagnostic may be required to allow approval of some of our products. However, technical difficulties or other issues could delay or disrupt the development of our products.

U.S. Patent Term Extension and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of a drug or biologic, some U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits extension of a patent term of up to five years beyond the normal expiration date of the patent as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension. An NDA or BLA applicant may apply for extension of patent term for its currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FD&C Act also can delay the submission or the approval of certain applications. The FD&C Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity 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. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (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. The FD&C Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) 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 conditions of use associated with the new clinical investigations and 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 a full NDA. However, an applicant submitting a full 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.

Biosimilars and Exclusivity

Certain of our product candidates are regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), as part of the ACA. This amendment to the PHS Act, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor. The law is complex and is still being interpreted and implemented by the FDA.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs for drugs and biologics. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect such operations include:

- the federal Anti-Kickback Statute is a criminal statute which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties;

- federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. Several pharmaceutical and other healthcare companies have been prosecuted under these

laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent;

- HIPAA which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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 Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and its implementing regulations, impose certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed healthcare practitioners, and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members);

- the FCPA which prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business; and

- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; 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 that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines,

disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Environmental Regulation

The Company may also be subject to foreign and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that the Company will not incur significant costs to comply with laws and regulations in the future or that such laws or regulations will not have a material adverse effect upon the Company's business, financial condition and results of operations.

Pricing and Reimbursement

Precision therapeutic products and their accompanying companion diagnostic are largely paid for based on third-party payor reimbursement. In the United States., concurrent with approval for commercialization of such therapeutic products by the FDA, each therapeutic product is assigned a product code, and its associated companion diagnostic assigned a similar code, or CPT. Each product code and CPT is then assigned a reimbursement level by CMS. Third-party insurance payors typically establish a specific fee to be paid for each code submitted. Third-party payor reimbursement policies are generally determined with reference to the reimbursement for CPT codes for Medicare patients which themselves are determined on a national basis by CMS.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. 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.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The U.S. government, state legislatures, and foreign governments have continued implementing cost- containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from

countries where they may be sold at lower prices than in the United States. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Increasingly, third-party payors are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any products that we commercialize and, if reimbursement is available, the level of reimbursement.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Parallel to this regulatory reimbursement scheme in the United States., other countries also regulate reimbursement similarly to the United States. 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 Therefore, it is important that ProMIS establish for its human diagnostic and therapeutic products reimbursement schemes, which provide ultimate financial payment for ProMIS' products consistent with its business plan.

Healthcare Reform Measures

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The U.S. 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.

The Affordable Care Act (ACA) substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. Among other things, the ACA subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers; ; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (a requirement that was later replaced by the Part D Manufacturer Discount Program under the Inflation Reduction Act of 2022); and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted since passage of the ACA.

- The Budget Control Act of 2011 and subsequent legislation, among other things, resulted in reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year through 2031.

- The American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- The United States Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA included substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements

on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. Under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one or more orphan designations and for which the only approved indications are for rare diseases or conditions. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect the IRA will have on our business and the pharmaceutical industry in general is not yet known.

- The One Big Beautiful Bill Act of 2025 (OBBBA), for example, imposed significant reductions in Medicaid funding, additional work requirements for Medicaid recipients, and more frequent reenrollment requirements. These changes are expected to place substantial pressure on state Medicaid budgets, reduce enrollment, and limit covered services, which could decrease utilization of, and reimbursement for, our products, if approved.

The costs of drugs have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation (MFN) price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price. In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing, and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model (GLOBE) for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Further legislative and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, allowing the federal government to directly

negotiate drug 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.

Individual States in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, if approved, or additional pricing pressures.

Impact of the current U.S. administration on FDA and NIH policies:

Changes in U.S. government administration and potential reforms to the FDA and NIH may adversely affect the regulatory environment and our business operations.

The regulatory landscape for biotechnology and pharmaceutical companies is heavily influenced by policies set by the U.S. government, including the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). With the current presidential administration implementing new priorities, there is a heightened risk of regulatory uncertainty, policy shifts, and potential reform efforts that could impact drug development, clinical trial oversight, and funding for biomedical research.

Proposed changes to FDA approval processes, accelerated pathways, or regulatory requirements could result in delays, increased costs, or additional hurdles in advancing our clinical programs, including the PRECISE-AD Phase 1b trial in Alzheimer's disease. Additionally, modifications to NIH funding priorities or grant allocations could impact broader research collaborations and the availability of scientific resources that support our programs.

If the current administration enacts policies that slow down clinical trial approvals, alter market access dynamics, or introduce new compliance burdens, our ability to efficiently develop and commercialize our therapies could be adversely affected. We continue to monitor regulatory developments and engage with industry stakeholders to navigate potential challenges; however, there can be no assurance that future policy changes will not materially and negatively impact our business, financial condition, or results of operations.

Regulation Outside of the United States

In addition to regulations in the United States, we may be subject to a variety of regulations in foreign jurisdictions that govern, among other things, clinical trials and any commercial sales and distribution of our products, if approved, either directly or through our distribution partners. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical trials or marketing and sale of the product in those countries. The foreign regulatory approval process and the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Some foreign jurisdictions have a drug product approval process similar to that in the U.S., which requires the submission of a clinical trial application much like the IND prior to the commencement of clinical studies. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Moreover, some nations may not accept clinical studies performed for U.S. approval to support approval in their countries or require that additional studies be performed on natives of their countries. In addition, in certain foreign markets, the pricing of drug

products is subject to government control and reimbursement may in some cases be unavailable or insufficient. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or any future partner of ours. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Commercial Marketing Plans and Strategies

ProMIS currently does not intend to market its therapeutic products or any companion diagnostics it develops that require extensive distribution channels. Instead, ProMIS expects to license to, or enter into strategic alliances with, pharmaceutical entities that are equipped to manufacture and/or market ProMIS' products through their distribution networks. ProMIS may license some or all of its patent rights to more than one company to achieve the fullest development, marketing and distribution of its products. To this end, ProMIS intends to continue to develop and improve its proprietary technologies and to expand the applications of its technologies in the healthcare markets.

Generate Product Revenues

Revenues, if any, from its precision therapeutics pipeline and companion diagnostics are expected to be generated from research funding, license fees, milestone payments, co-development funding, and royalties from partnerships to be completed by ProMIS with selected third-party, multi-national health care firms. As of the date of this form, ProMIS has not generated any significant product revenues.

Develop Collaborative Customer-Funded Commercialization Agreements

In order to increase market exposure of its products and to capitalize on a partner's clinical development competencies, market position, and distribution capabilities, ProMIS intends to develop its projects with collaborative commercial partners who will fund further product development projects incorporating ProMIS' technology. These collaborative arrangements typically will provide for a jointly funded development project and contemplate a licensing arrangement (which may be entered into at the same time as the development project or at a later date) under which, if a project is commercialized by the collaborative partner, ProMIS would potentially receive license fees, royalty payments from product sales and manufacturing revenue. ProMIS believes that such arrangements with major commercial partners will serve to validate its proprietary technologies in human healthcare areas and thereby assist ProMIS in attracting additional licensing arrangements on favorable terms.

Enhance Out-licensing of ProMIS Requirements

Where practical, ProMIS will outsource its product manufacturing and has explored and will continue to evaluate the possibility of entering into strategic manufacturing alliances with appropriate third parties.

Competition

Human Healthcare Products Competition

ProMIS will compete with many large and small pharmaceutical companies that are developing and/or marketing therapeutic compounds for AD, ALS and/or PD. Many large pharmaceutical companies and smaller biotechnology companies maintain well-funded research departments concentrating on therapeutic approaches to neurodegenerative diseases. ProMIS expects substantial competition from these companies as they develop different and/or novel approaches to the treatment of these diseases. Some of these approaches may directly compete with the technology that ProMIS is currently developing.

Although we believe PMN310 currently is differentiated from other products on the market or in development, if approved, PMN310 will compete with therapies currently approved for the treatment of patients with AD, which have primarily been developed to treat the symptoms of AD rather than the underlying cause of the disease, such as memantine and cholinesterase inhibitors. PMN310 may also compete with one or more potentially disease-modifying therapeutics that

target Aβ or amyloid plaques. Biogen's aducanumab (Aduhelm) was approved by the FDA in June 2021 under the Accelerated Approval pathway, but commercialization was discontinued in January 2024.

Eisai and Biogen's lecanemab (Leqembi) and Lilly's donanemab (Kisunla) received traditional approval in 2023 and 2024, respectively. In many therapeutic categories, after initial approvals validate a general mechanistic approach, competitive dynamics are driven by relative safety, efficacy, convenience, and cost effectiveness. We expect this will be the case in the anti-amyloid immunotherapy category.

Other companies known to be developing therapies with Aβ/amyloid plaque-related targets include Alzheon, Inc., Alzinova AB, Chugai Pharmaceutical Co. Ltd., Cognition Therapeutics, Inc., Eisai Co., Ltd., Eli Lilly and Company, Grifols, S.A., KalGene Pharmaceuticals, Inc., Neurimmune AG, Novartis AG, Acumen Pharmaceuticals Inc., Prothena Biosciences, Inc., Roche Holding AG (including Genentech, its wholly owned subsidiary) and Wren Therapeutics, Inc. Additionally, PMN310, if approved, may also compete with other potential therapies intended to address underlying causes of AD that are being developed by several companies, including AbbVie Inc., AC Immune SA, Alector, Inc., Anavex Life Sciences Corp., Annovis Bio, Inc., Athira Pharma, Inc., Biohaven Pharmaceuticals, Inc., Cortexyme, Inc., Denali Therapeutics, Inc., Johnson & Johnson (including Janssen, its wholly-owned subsidiary) and Takeda Pharmaceutical Co. Ltd. Some of these competitors are developing therapies that either seek to block the aggregation of amyloid oligomers (for example, Alzheon, Inc.), or mitigate the toxicity of amyloid oligomers (for example, Cognition Therapeutics, Inc.). These and other therapies may end up being used as complementary therapies in clinical practice, in addition to antibodies targeting aggregated amyloid.

In the intense competitive environment that is the human pharmaceutical industry, those companies that complete clinical trials, obtain regulatory approval and commercialize their therapeutic products first may enjoy competitive advantages. ProMIS believes that it will develop compounds with characteristics that may enable them, if fully developed, to have a market impact. A number of major human pharmaceutical companies have significant programs to develop drugs for the treatment of neurodegenerative disease. These companies include Eisai/Pfizer, Novartis, Merck, Genentech, Lilly, Biogen, Amgen and Johnson & Johnson.

Proprietary Protection

ProMIS has acquired the rights to certain proprietary discovery platforms for the identification of proteins involved in misfolding diseases embodied in various national and international patent applications. ProMIS has also filed international patent applications related to immunotherapy targeting toxic forms of TDP-43 and RACK1 for ALS, toxic oligomers of Aβ for AD and toxic aggregates for a-syn for PD to further protect its intellectual property rights related to its therapeutic programs. In addition, the Company has obtained proprietary rights to a computational algorithm (EpiSelect™) for identification of disease-specific epitopes (DSEs) in protein misfolding diseases as well as predicted DSEs against multiple disease targets. ProMIS intends to aggressively protect the commercial applications for diagnostic, therapeutic and prophylactic applications of these discoveries. In addition, ProMIS has developed know-how, which it may elect to keep as trade secrets and not publicly disclose in patent applications.

Human Capital Management

ProMIS seeks to hire qualified scientists and key employees as needed. As of December 31, 2025, the Company employed ten full-time employees and one part-time employee. The remainder of the scientists and key personnel had consulting agreements with ProMIS.

Our future success depends on our ability to attract, develop and retain key personnel, maintain our culture, and ensure diversity and inclusion in our board, management and broader workforce. Our human resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. As these areas directly impact our ability to compete and innovate, they are key focus areas for our board of directors and senior executives.

Corporate Structure

ProMIS Neurosciences Inc. was incorporated on January 23, 2004 under the name 4203801 Canada Inc. pursuant to the Canada Business Corporations Act (CBCA). The Company changed its name to Amorfix Life Sciences Ltd. on August 24, 2004 and to ProMIS Neurosciences Inc. effective July 8, 2015. On July 13, 2023, the Company continued its existence from a corporation incorporated under the CBCA into the Province of Ontario under the Business Corporations Act (Ontario) (OBCA) (Continuance). The Continuance was approved by the Company's shareholders at the Company's 2023 Annual Meeting of Shareholders held on June 29, 2023.

On November 17, 2025, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 25:1, effective November 28, 2025 (the 2025 Reverse Share Split). All information included in this Annual Report on Form 10-K has been adjusted to reflect the 2025 Reverse Share Split. Unless otherwise stated herein, all share and per share numbers relating to the Company's Common Shares prior to the effectiveness of the 2025 Reverse Share Split have been adjusted to give effect to the 2025 Reverse Share Split, including the consolidated financial statements and notes thereto.

Our head office is located at 1920 Yonge Street, Suite 200, Toronto, Ontario, Canada M4S 3E2 and our registered and records office is located at 1055 West Georgia Street, Vancouver, British Columbia, Canada V6E 4N7. Our telephone number is (416) 847-6898 and our website address is www.promisneurosciences.com. The information provided on our website is not part of this Annual Report on Form 10-K.

We own or have rights to various trademarks, service marks and trade names that we use in connection with the operation of our business. This Annual Report on Form 10-K may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this Annual Report on Form 10-K is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K may appear without the ®, ™ or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Unless the context indicates otherwise, references in this prospectus to the "Company," "ProMIS," "we," "us," "our," and similar terms refer to ProMIS Neurosciences Inc. and its consolidated subsidiary.

Unless otherwise indicated, all references to "$" or "US$" in this Annual Report on Form 10-K refer to U.S. dollars, and all references to "C$" refer to Canadian dollars.

Available Information

We will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site, http://www.sec.gov, containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Investors and others should note that we announce material information to our investors using our investor relations website (https://www.promisneurosciences.com/investors), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media, including LinkedIn and our Twitter (@ProMISInc), to communicate with the public about our company, our business, our product candidates and other matters. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website. Information that is contained in and can be accessed through our website or our social media posts are not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

Item 1A. Risk Factors

Investors should carefully consider the following risk factors, together with all of the other information included in this Annual Report on Form 10-K, before making an investment decision. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. You should also carefully consider the following risk factors in addition to the other information included herein, including matters addressed in the section entitled "Cautionary Note Regarding Forward-Looking Statements," and all other information in the Company's other public filings prior to making an investment decision. We may face additional risks and uncertainties that are not presently known to us or that we currently deem immaterial, which may also impair our business or financial condition. Additionally, investors should not interpret the disclosure of a risk to imply that the risk has not already materialized. The following discussion should be read in conjunction with the financial statements and notes to the financial statements included herein.

Risks Related to the Development of Our Product Candidates

Our product candidates are still in the early stages of development and there is significant uncertainty that any such products will ever be approved .

Our product candidates are at an early stage of development. Significant additional investment in research and development, product validation, technology transfer to manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates is required prior to commercialization. There can be no assurance that any such product candidates will actually be developed and, if developed, will be approved. The development and regulatory processes may require access to rare biofluid and tissue samples from people and animals which may not be available to us in sufficient amounts or in a timely fashion to allow us to complete the development or receive regulatory approval of any product candidate or process. A commitment of substantial time and resources is required to conduct research and clinical trials if we are to complete the development of any product candidate. It is not known whether any of these product or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products, if approved, can be produced in commercial quantities at reasonable costs and be successfully marketed, or if our investment in any such products will be recovered through sales or royalties.

We expect to incur substantial capital expenditures in connection with the development of our product candidates. If we fail to successfully develop and sell all or any of our product candidates, if approved, then we will not earn any return on our investment in these future products, which will adversely affect our results of operations and could adversely affect the market price of the Common Shares. Our success in developing and selling new products will depend upon multiple factors, including:

- our ability to develop safe and effective products;
- our serology assays and vaccines achieving the desired sensitivity for antibody-based immunity and immune response, as applicable;
- acceptance of the product by the medical community and by patients and third-party payors;
- inherent development risks, such as the product proving to be unsafe or unreliable, or not having the anticipated effectiveness; and
- our ability to develop repeatable processes to manufacture new products in sufficient quantities.

If any of these factors cannot be overcome, we may not be able to develop and introduce our products in a timely or cost-effective manner, which could adversely affect our future growth and results of operations. Our failure to develop and obtain approval of our product candidates could adversely affect the market price of the Common Shares.

Our business is heavily dependent on the successful development, regulatory approval and commercialization of PMN310 and any future product candidates that we may develop or acquire, including PMN442 and PMN267.

We currently have no products approved for sale, and our lead product candidate is in early stages of development. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, the advancement of PMN310. However, given our stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

The clinical and commercial success of PMN310 and any future product candidates that we may develop or acquire will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND enabling studies and successfully submit INDs or comparable applications;
- 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 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 successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the U.S. 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;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- our current clinical development plans for PMN310 may change as a result of clinical trial outcomes and future interactions with the FDA.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

Our approach to the potential treatment of AD is based on a novel therapeutic approach, which exposes us to unforeseen risks.

There is no current scientific or general consensus on the causation of AD or method of action to treat AD. We have discovered and are developing PMN310, a humanized antibody that selectively targets AβO, or AβOs, to treat AD. Our approach is based on research on AβOs, globular assemblies of the Aβ peptide that are distinct from other forms of amyloid. AβOs have gained scientific acceptance as primary toxins involved in the initiation and propagation of AD pathology. Based on the results of our studies to date, we believe PMN310 is different from current and prior clinical-stage anti-amyloid drugs and product candidates based on its selectivity for AβOs. We believe that this is a novel mechanism which has the potential to provide more favorable outcomes, as compared to approved therapies and product candidates in development and may potentially slow disease progression. However, we may ultimately discover that PMN310 does not possess properties required for therapeutic effectiveness. We may spend substantial funds attempting to develop PMN310 or other product candidates and never succeed in doing so.

The market for any products that we successfully develop, if any, will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it would cost to commercially manufacture PMN310, if approved, and the actual cost to manufacture PMN310 or any drug we develop in the future could materially and adversely affect the commercial viability of the drug. We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. If we do not successfully develop PMN310 or any other drug we develop with drug product that can be reliably and economically manufactured at scale, we will not become profitable, which would materially and adversely affect the value of our Common Shares.

We may not successfully expand our pipeline of product candidates, including by pursuing additional indications for PMN310 or by in-licensing or acquiring additional product candidates for other diseases.

A key element of our strategy is to build and expand our pipeline of product candidates, including by developing PMN310 for the treatment AD, and by identifying other product candidates. In addition, we may in-license or acquire additional product candidates for other diseases. We may not be able to identify or develop additional product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in-license or acquire may not be suitable for clinical development. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We cannot guarantee that we will be successful in identifying additional potential drug candidates, or that we will be able to successfully identify and in-license new and valuable product candidates from other parties.

Nonclinical and clinical drug development involves a lengthy, expensive and uncertain process. The results of nonclinical studies and early clinical trials are not always predictive of future results. PMN310 or any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of product candidates is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete nonclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of nonclinical studies and early clinical trials are not necessarily predictive of future results and PMN310, or any other product candidate that we may develop, may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical industry have suffered setbacks in the advancement of their product candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding results in earlier nonclinical studies or clinical trials. In addition, the results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. This is particularly true in AD, where failure rates historically are higher than in most other disease areas.

In the event of negative or inconclusive results, we may decide, or regulatory authorities may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from clinical trials and nonclinical studies is susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

If we are unable to complete nonclinical studies or clinical trials of PMN310 or future product candidates, due to safety concerns or otherwise, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for PMN310 or any future product candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those product candidates. Moreover, if we are not able to differentiate our product candidate against other approved product candidates within the same class of drugs, or if any of the other circumstances described above occur, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Clinical failure can occur at any stage of clinical development and our Company has not completed any pivotal clinical trial or submitted a BLA.

We are early in our development efforts for PMN310 and we have only completed one Phase 1a clinical trial. We will need to successfully complete our ongoing and planned clinical trials, including pivotal clinical trials, in order to obtain FDA approval to market PMN310 or any other product candidate we seek to develop. Carrying out clinical trials and the submission of a successful BLA is a complicated process. Although members of our team have significant experience in clinical development of drugs through regulatory approval, as an organization, we have limited experience in conducting any clinical trials with PMN310, we have limited experience in preparing regulatory submissions with PMN310 and we have not previously submitted a BLA.

In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of PMN310 will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of PMN310 or any other product candidate. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our current or planned clinical trials, could prevent us from or delay us in commercializing PMN310 or any future product candidates we may develop, and failure to successfully complete any of these activities in a timely manner could have a material adverse impact on our business and financial performance.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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

- regulatory authorities, Institutional Review Boards (IRBs) or Ethics Committees (ECs), may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or we may fail to reach a consensus with regulatory authorities on trial design;
- regulatory authorities in jurisdictions in which we seek to conduct clinical trials may differ from each other on our trial design, and it may be difficult or impossible to satisfy all such authorities with one approach;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining IRB or independent EC approval at each clinical trial site;
- clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulatory authorities 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 our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- difficulties in having subjects complete a clinical trial or returning for post-treatment follow-up;
- changes to clinical trial protocols;

- our third-party contractors, including clinical investigators, contract manufacturers and vendors may fail to comply with applicable regulatory requirements, lose their licenses or permits, or otherwise fail, or lose the ability to, meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- regulatory authorities or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or 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, and we may lack adequate funding to continue one or more clinical trials;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- clinical trial sites may deviate from clinical trial protocol or drop out of a clinical trial; and

- occurrence of serious adverse events in trials of the same class of agents conducted by other companies.

Adverse side effects, properties or other safety risks associated with PMN310, PMN267, PMN442 or any future product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is possible that there may be side effects and adverse events associated with the use of PMN310, PMN267, PMN442 or any future product candidates we may develop. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics as the clinical trials progress to greater exposures and a larger number of patients. Undesirable side effects caused by, or unexpected or unacceptable characteristics associated with, PMN310, PMN267, PMN442 or any future product candidates we may develop, could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities, or IRBs for a number of reasons. We may also elect to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for such product candidate if approved. If we elect or are required to further delay, suspend or terminate any clinical trial of any product candidates we may develop, the commercial prospects of such product candidates will be harmed and our ability to generate drug revenues from any such product candidates will be delayed or eliminated.

It is possible that, as we test our product candidates in clinical trials, or as the use of a product candidate becomes more widespread if it receives regulatory approval, we may identify additional adverse events that were not identified or not considered significant in our earlier trials. If such side effects become later known in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly. If we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approval of a product candidate;

- we may be required to recall a drug or change the way such drug is administered to patients;

- regulatory authorities may require additional warnings or statements in the labeling, such as a boxed warning or a contraindication or issue safety alerts, press releases or other communications containing warnings or other safety information about the product candidate, for example, field alerts to physicians and pharmacies;

- regulatory authorities may require us to implement a REMS to ensure that the benefits of the drug outweigh its risks, which 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;

- we may be required to change the way a drug is distributed or administered, conduct additional clinical trials or be required to conduct additional post-marketing studies or surveillance;

- we may be subject to regulatory investigations and government enforcement actions;

- we may decide to remove such product candidates, if approved, from the market;

- we could be sued and held liable for harm caused to patients;

- sales of the drug may decrease significantly or become less competitive; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

We may experience delays or difficulties in the enrollment and retention of patients in clinical trials, which could delay or prevent our receipt of regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates or approved products for the conditions for which we are developing our product candidates.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the severity and difficulty of diagnosing the disease under investigation;

- the eligibility and exclusion criteria for the trial in question;

- the size of the patient population and process for identifying patients;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- the design of the trial protocol;

- the perceived risks and benefits of the product candidate in the trial, including relating to cell therapy approaches;

- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;

- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by any global health crisis, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Interim, top-line and preliminary results from our planned clinical trials that we may announce or publish from time to time may change as more data become available and is subject to audit and verification procedures that could result in material changes in the final data.

From time to time, as we continue existing and initiate new clinical trials, we may publish interim, top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results 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 reported. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our Common Shares to fluctuate significantly. 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. 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.

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 development 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 meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from actual 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 prospects.

We cannot be certain that PMN310, PMN267, PMN442 or any of our future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We currently have no product candidates approved for sale and we cannot guarantee that we will ever have marketable product candidates. Our ability to generate revenue related to sales of PMN310, PMN267 and PMN442, if ever, will depend on the successful development and regulatory approval of such product candidates.

The development of a product candidate and its approval and commercialization, including the product candidate's design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to extensive regulation by the FDA, the EMA and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the U.S., Europe or other countries until we receive approval of a BLA from the FDA or MAA from the EMA, respectively. We have not submitted any marketing applications for any product candidate.

BLAs and MAAs, and other foreign equivalents must include extensive nonclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. BLAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a BLA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates.

Even if a drug is approved, the FDA or the EMA, or other foreign equivalent, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the U.S. and Europe also have requirements for approval of product candidates with which we must comply prior with marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the U.S., Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of drug development and the emergence of new information regarding PMN310, PMN267, PMN442 or other product candidates we may develop in the future. Also, regulatory approval for any of our product candidates may be withdrawn.

Before we submit a BLA to the FDA or a MAA to the EMA for a product candidate, we will be required to successfully complete our clinical trials. The FDA generally requires two pivotal clinical trials to support approval. In addition, we must scale up manufacturing and complete other standard nonclinical and clinical studies. We cannot predict whether clinical trials will be successful or whether regulators will agree with our conclusions regarding the nonclinical studies and the clinical trials we conduct. The FDA, EMA, and other comparable regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop and may decide that our data are insufficient for approval or require additional preclinical, clinical, or other data. The U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes.

Our lead product candidate, PMN310, is being developed for the treatment of AD, a disease that has seen limited success in drug development.

Efforts by biopharmaceutical and pharmaceutical companies in treating AD have seen limited success in drug development. Only three disease-modifying therapeutic options have been approved by the FDA. Biogen's Aduhelm, a mAb administered via infusion, received Accelerated Approval from the FDA on June 7, 2021 but commercialization was discontinued in January 2024. Eisai and Biogen's lecanemab (Leqembi) and Lilly's donanemab (Kisunla) received

traditional approval in 2023 and 2024, respectively. We cannot be certain that our approach will lead to the development of approvable or marketable products. With the exception of Leqembi and Kisunla, the only available FDA-approved drugs to treat patients with AD address the symptoms of the disease. Since 2003, over 500 clinical studies have been completed and only Aduhelm (discontinued), Leqembi and Kisunla have been approved by the FDA as disease-modifying therapeutic options. As a result, the FDA has a limited set of products to rely on in evaluating PMN310. This could result in a longer than expected regulatory review process, increased expected development costs or the delay or prevention of commercialization of PMN310 for the treatment of AD.

In addition to the significant uncertainty related to insurance coverage and reimbursement of all newly- approved products, there is greater uncertainty for products approved for the treatment of AD. For example, the yearly wholesale acquisition out of pocket cost of the maintenance dose of Aduhelm was $28,200. CMS issued a draft determination that proposes to cover the cost of anti-amyloid monoclonal antibodies, including Aduhelm, only in the context of clinical trials approved by CMS or by the National Institutes of Health. These include only randomized controlled trials conducted in hospital-based outpatient settings, and require patient diversity reflecting that of the U.S. population diagnosed with AD. In April 2022, CMS confirmed this determination and announced that it would deny routine payment for Aduhelm and finalized a strict policy to require patients to enroll in clinical trials for the government to cover the drug. Biogen announced discontinuation of Aduhelm commercialization in January 2024. In contrast, Leqembi was priced at $26,500 and is covered by Medicare Part B and some private insurers.

We may in the future conduct clinical trials for our product candidates outside the U.S., and the FDA, EMA and other foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. by FDA, or of data collected outside the jurisdiction by any foreign regulatory body, 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 U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly. There can be no assurance that the FDA, EMA or any other foreign regulatory authority will accept data from trials conducted outside of their jurisdiction. If the FDA, EMA 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.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of nonclinical studies and clinical trials and the submission of regulatory filings, including BLA submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

We may develop PMN310, PMN442, PMN267 and future product candidates for use in combination with other therapies, which could expose us to additional regulatory risks.

We may develop PMN310, PMN442, PMN267 and future product candidates for use in combination with one or more other approved therapies for the disease state being studied. Even if any product candidate we develop were to receive

marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics.

Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates.

Risks Related to Our Financial Position and Capital Needs

We have incurred losses since inception and we anticipate that we will incur continued losses for the foreseeable future. We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of biopharmaceutical therapeutic candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies of our development programs, conduct existing and initiate new clinical trials for our therapeutic candidates and seek regulatory approval for our current therapeutic candidates and any future therapeutic candidates we may develop. If we obtain regulatory approval for any of our therapeutic candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our therapeutic candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We had operating losses of $40.2 million and working capital of approximately ($1.2) million as of and for the year ended December 31, 2025. We will require substantial additional funds for further research and development, current and planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, the marketing and sale of our products. Our ability to raise additional financing and maintain operations in the future could be at substantial risk and there can be no assurance that additional funding or partnerships will be available on acceptable terms, if at all, that would foster successful commercialization of our products. Failing to raise capital when needed or on attractive terms could force us to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We may attempt to raise additional funds for these purposes through public or private equity or debt financing, use of “at-the-market” offerings, collaborations with other biopharmaceutical companies and/or from other sources.

We have no product candidates approved for commercial sale, we have never generated any revenue from sales and we may never be profitable.

We have no product candidates approved for sale, have never generated any revenue from sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have not recorded any revenues from the sale of biopharmaceutical products. As of December 31, 2025, we had a deficit of $130.4 million. The cumulative deficit incurred from when we changed our name and focus in July 2015, through December 31, 2025 was $100.1 million. We expect to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its product candidates. We also expect to incur losses unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations.

We have devoted most of our financial resources to research and development of PMN310, including our clinical and nonclinical development activities of PMN310, and corporate overhead. We expect that it will be several years, if ever, before we have a product candidate approved and ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, PMN310 and any other product candidate we may develop in the future, prepare for and begin the commercialization of any approved product candidates and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Further, these net losses may fluctuate significantly from quarter-to-quarter or year-to-year. To become and remain profitable, we must develop and eventually commercialize PMN310 or another drug with significant revenue.

We may never succeed in developing a commercial drug and, even if we succeed in commercializing one or more product candidates, we may never generate revenues that are large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown challenges. Because of these numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis, and we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates.

Risks Related to the Commercialization of Our Product Candidates

Successful commercialization of our product candidates, if approved, will depend on a number of factors and we cannot guarantee that we will be able to successfully commercialize our products.

Successful commercialization of our products, if at all, will depend on a number of factors, including our ability to:

- raise sufficient capital to fund future commercialization efforts;
- build a commercial team and supporting organizational infrastructure;
- obtain necessary licenses, on commercially reasonable terms, for certain offerings we may contemplate;
- establish partnerships and alliances with third parties to secure commercial capabilities that we may not wish to build;
- market and distribute our products;
- distinguish our products from others available on the market;
- obtain any necessary regulatory approvals for our facilities, product candidates and processes;

- gain reimbursement by third-party payors, such as private health insurers, managed-health organizations, and state-sponsored health insurance plans for each jurisdiction in which our products are offered;
- educate physicians and change physician behavior to secure clinical adoption of our products;
- promote awareness of our products to increase market penetration; and
- publish in peer-reviewed journals.

There is no assurance that we will be successful in these areas. Any failure or delay in such areas could have a material adverse impact on our business, financial condition, results of operations and prospects.

The market opportunities for PMN310, PMN267, PMN442 and future product candidates, if approved, may be smaller than we anticipate.

We expect to seek approval for product candidates for various neurodegenerative diseases and other misfolded protein diseases. 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 our product candidates after FDA approval, the potential target populations may be too small to consistently generate revenue, and we may never achieve profitability without obtaining marketing approval for additional indications.

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

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

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from governmental healthcare plans or third-party payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, if approved for commercial sale;

- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- limitations or warnings contained in the FDA-approved labeling for our products;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure that our current or future product candidates, if approved, will achieve broad market acceptance among physicians, patients, healthcare payors and others in the medical community. Even if we receive regulatory approval to market any of our product candidates, we cannot assure 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.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process to commercialize our potential products, which may not be successful.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our third-party manufacturers will be successful in establishing a larger-scale commercial manufacturing process for our product candidates which achieves our objectives for manufacturing capacity and cost of goods. In addition, there is no assurance that any 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 successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those drugs and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage

and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. For more information regarding the risks related to insurance coverage and reimbursement please see "*Business — Government Regulation — Pricing and Reimbursement*."

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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 U.S., 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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the U.S., 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 U.S. 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. Outside the U.S., 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.

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

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

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the U.S. and foreign jurisdictions, if approved, we intend to make arrangements with third parties to perform these services, and we may not be successful in doing so. 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 approved. If we are not successful in commercializing our product candidates or any future product candidates, if approved, either on our own or through arrangements with third parties, we may not be able to generate any product revenue and we would incur significant additional losses.

Risks Related to Our Dependence on Third Parties

We will rely on third parties to supply components, research, develop, test, and manufacture our product candidates and market these product candidates, if approved. The loss of any of these third-party relationships or the failure of any of them to meet their obligations to us could affect our ability to develop and obtain approval of our product candidates in a timely manner.

Our activities will require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of our products. We intend to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that we will be able to establish such additional collaborations on favorable terms, if at all, or that our current or future collaborations will be successful. Failure to attract commercial partners for our products may result in substantial clinical testing, manufacturing and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

Should any collaborative partner fail to develop, manufacture, or successfully commercialize any product to which we have rights, or any partner's product to which we will have rights, our business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by our programs.

Furthermore, we will hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on acceptable conditions. We intend to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, *inter alia*, a requirement to make milestone payments, which may be substantial. We will also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications.

We intend to rely on CROs and other third parties to conduct, supervise and monitor a significant portion of our research and nonclinical testing and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We intend to engage CROs and other third parties to conduct our planned nonclinical studies or clinical trials, and to monitor and manage data. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, in the future. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our clinical trials will not be our employees, and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and

resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We plan to rely on these parties for execution of our nonclinical studies and clinical trials and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs, which are standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMPs conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, or may result in fines, adverse publicity and civil and criminal sanctions.

We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval for PMN310 or any other product candidate we develop.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

If any of our third-party manufacturers encounter difficulties in production of PMN310, PMN267, PMN442 or any future product candidate we develop, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or, if approved, for commercial sale could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing PMN310, PMN267, PMN442 and any other product candidate we may develop are highly-regulated and subject to multiple risks. As product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our third-party manufacturers, such facilities may need to be

closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In order to conduct clinical trials of our product candidates, or supply commercial product candidates, if approved, we will need to manufacture them in both small and large quantities. We currently rely on third parties to manufacture our product candidates, and our manufacturing partners will have to modify and scale-up the manufacturing process when we transition to commercialization of our product candidates, if approved. Our manufacturing partners may be unable to successfully modify or scale-up the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale-up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any product candidates that we may develop will be subject to FDA, EMA and foreign regulatory requirements, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with cGMPs on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce product candidates in accordance with the requirements of the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such product candidates. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our third-party contract manufacturers will be able to manufacture the approved product in accordance with the requirements of the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

We will likely seek collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates, including PMN310, PMN267 and PMN442. Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our future products.

We will likely seek third-party collaborators for the commercialization of PMN310, PMN267, PMN442 and any of our future product candidates, in the U.S. and may enter into collaboration agreements for the development and commercialization of any of our product candidates outside the U.S. In the U.S., commercialization partners are likely to include large biotechnology or pharmaceutical companies. Our likely collaborators outside the U.S. would most likely include regional and national pharmaceutical companies and biotechnology companies. If we enter into such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;

- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the U.S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business

combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates, and other proprietary technologies if approved, may be adversely affected.

Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, and other proprietary technologies we develop. If we are unable to obtain or maintain patent protection with respect to our product candidates, and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific, and factual questions and has been the subject of frequent litigation in recent years.

As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued that protect our product candidates and other proprietary technologies we may develop or that effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in many jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we may own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our product candidates and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- issued patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or may otherwise not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our product candidates;

- other parties may have designed around our claims or developed technologies that may be related or competitive to ours, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications and/or patents, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position;

- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any product candidate that we may develop;

- because patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates and other proprietary technologies and their uses;

- an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of any application with an effective filing date before March 16, 2013;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by

U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates in those countries.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, or maintain 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. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to file patent applications for these inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable;
- our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire; or
- the patents of others may have an adverse effect on our business.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third-party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

We cannot be certain that claims in an issued patent covering our product candidates will be considered patentable by the USPTO, courts in the U.S., or by patent offices and courts in foreign countries. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. Patent applications that we file or in-license may fail to result in issued patents with claims that cover our product candidates in the U.S. or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by our patents with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidates.

For U.S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the "first to file" provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. It remains unclear what impact the America Invents Act will have on the operation of our

business. As such, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the U.S., provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. When the terms of all patents covering our product candidates expire, our business may become subject to competition from competitive products, including biosimilar version of our products.

Our product candidates are protected by certain patents or patent applications, which expire at varying times. We cannot be certain that we will file and, if filed, obtain patent protection for our product candidates beyond our rights in our current patent portfolio. If we are unable to obtain additional patent protection on our product candidates, our primary protection from biosimilar market entries will be limited to regulatory biologic exclusivity.

If we do not obtain patent term extension for our product candidates our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of our product candidates, one or more of patents issuing from U.S. patent applications that we file or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term, or PTE, of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate, or SPC. If we encounter delays in our development efforts, including our future clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the license agreement;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and/or to secure our rights to the licensed intellectual property, our business, results of operations, financial condition, and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

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 non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes 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. In such an event, our competitors might be able to enter the market with similar or identical products or technology earlier than should otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in United States or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and enforcing patents in the biotechnology and pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States may, at any time, enact changes to its patent law and regulations, including by legislation, by regulatory rule-making, or by judicial precedent, that adversely affect the scope of patent protection available and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. Other countries may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement, and obtain injunctions and/or damages.

Further, the United States and other governments may, at any time, enact changes to law and regulation that create new avenues for challenging the validity of issued patents. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. 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 decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could

change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting, and defending patents on our product candidates, and other proprietary technologies we develop in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement of such patent protection 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.

The requirements for patentability may differ in certain countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors.

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 intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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 or pharmaceutical 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 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 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 or license.

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

We may be subject to claims that former employees (including former employees of our licensors), collaborators or other third parties have an interest in our patents rights, trade secrets, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. For example, we may have inventorship disputes arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. 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.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through in-licenses.

Presently we have intellectual property rights to our product candidates through a license from the UBC. Assuming this agreement remains in place, we could be required to pay a low to high single digit royalty on revenues to UBC in the future. Because our program may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for our product candidates. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application.

Moreover, we will likely have obligations under our current or future licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we have collaborated and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in

technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time-frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program. In addition, disputes may arise under our existing or future license agreements with these institutions or with other counterparties, which may, among other things, lead to the termination or renegotiation of these agreements, or otherwise require us to incur significant financial obligations.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition, and prospects for growth, could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including *inter partes* review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including *inter partes* review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third-party might assert are infringed by one of our current or future product candidates.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, compositions, formulations, methods of manufacture or methods for treatment related to our product candidates, or the use or manufacture of our product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our product candidates, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation;

- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and/or
- require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do either. Proving invalidity or unenforceability is difficult. For example, in the U.S., proving invalidity before federal courts requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from developing, manufacturing or selling our product candidates.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of 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 U.S., Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction, because:

- some patent applications in the U.S. may be maintained in secrecy until the patents are issued;
- patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or their uses;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims;
- patent applications in the U.S. are typically not published until 18 months after the priority date; and

- publications in the scientific literature often lag behind actual discoveries.

Furthermore, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies or product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates or future products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. 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. Any such patent application may have priority over one of our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If a third-party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third-party's patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing 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. 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 our product candidates, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

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 biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates, and other proprietary technologies. 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 involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties including competitors may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time- consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States, or if we require, but do not receive, the consent or cooperation of our licensors to enforce such intellectual property.

If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third-party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution, i.e., committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we or our licensors hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or 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 licensors. 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 or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference 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 litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our future 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.

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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights 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 have a substantial adverse effect on the price of our Common Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. 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.

Our ability to enforce our patent rights depends on our ability to establish standing in a court of competent jurisdiction. Whether a patent holder or licensee of a patent has standing can be uncertain and the considerations complex. However, if a licensor is required to be joined, and they are unwilling to do so, we may be unable to proceed with an infringement action.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent or patents that may issue from 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 initiate or seek some other non-litigious action or solution.

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

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and/or other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer, or third-party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

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 U.S. are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to

industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and/or consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets 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. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names, once registered, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, 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 affect our financial condition or results of operations.

Moreover, any names we may propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Similar requirements exist in Europe. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we 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.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

As of the date of this Annual Report on Form 10-K, neither our patents nor our product candidates are subject to march-in rights. However, some of our future patents may be generated through the use of U.S. government funding, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. For more information regarding the risks related to these laws and regulations please see "Business — Government Regulation — "U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices could, despite efforts to comply, be subject to challenge under current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In Loper Bright Enterprises v. Raimondo, for example, the court overruled Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act (APA). Additionally, in Corner Post, Inc. v. Board of Governors of the Federal Reserve System, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, Securities and Exchange Commission v. Jarkesy, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Finally, with the change in presidential administrations in 2025, there continues to be substantial uncertainty as to the extent and manner in which the current administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. This uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and could materially adversely impact our business and prospects.

Even if we obtain regulatory approval for PMN310, PMN442, PMN267 or any future product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain any regulatory approval for PMN310, PMN442, PMN267 or any future product candidates, such product candidates will be subject to ongoing regulatory requirements applicable to research, development, testing, manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record- keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for PMN310, PMN442, PMN267 or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the

drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to timely report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. 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.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. 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 if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of a product candidate, a regulatory authority may:

- issue a Form 483, an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- issue a safety alert, Dear Healthcare Provider letter, press release or other communication containing warnings or safety information about the product;
- mandate corrections to promotional materials and labeling or issuance of corrective information;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of products or product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize a product candidate, if approved, and harm our business, financial condition, results of operations and prospects.

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 U.S., numerous federal and state laws and regulations, including HIPAA, as amended by 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 similarly comprehensive privacy laws and regulations. For example, the California Consumer Privacy Act, or CCPA, established a comprehensive privacy framework for covered businesses and gives California residents certain privacy rights, including the right to access and delete their personal information, opt out of certain personal information sales or transfers, receive detailed information about how their personal information is used and limit the use and sharing of sensitive personal information. The CCPA provides for civil penalties, as well as a private right of action for certain data breaches, and created an agency specifically tasked with enforcing the CCPA, which may increase the risk of litigation. Similar consumer privacy laws have passed in numerous other U.S. states with several more expected to pass in the coming years. Like the CCPA, these laws grant consumers rights in relation to their personal information and impose new privacy and data security obligations on regulated businesses. These comprehensive privacy laws in different states in the country vary in their scope, application and enforcement, which may complicate compliance efforts. In addition some states have passed or proposed laws specifically regulating consumer health information. For example, Washington's My Health My Data Act (MHMDA), requires regulated entities to obtain consent to collect health information, grants consumers certain rights, including to request deletion, and provides for robust enforcement mechanisms, including a private right of action for consumer claims. At the federal level, the FTC has used its authority over "unfair or deceptive acts or practices" to impose stringent requirements on the collection and disclosure of sensitive categories of personal information, including health information. Moreover, the FTC's expanded interpretation of a "breach" under its Health Breach Notification Rule could impose new disclosure obligations that would apply in the event of a qualifying breach.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. The federal government has taken steps to restrict data transactions involving certain sensitive data categories – including health data, genetic data, and biospecimens – with persons or entities affiliated with countries of concern. For example, the Department of Justice's January 8, 2025, Rule on Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons prohibits transfers of data including health data, genetic data, and biospecimens, to countries of concern, including China. The rule also prohibits covered businesses from granting access to certain investment agreements, employment agreements and vendor agreements involving such data to countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, may result in exclusion from participation in federal and state programs and may restrict our ability to use certain vendors, sites, investigators, or service providers in global clinical trials.

Foreign data protection laws may also apply to health-related and other personal information we process. For example, the collection and use of personal information (including health data) in Europe are governed by the provisions of the EU General Data Protection Regulation (EU GDPR) as well as other national data protection legislation in force in relevant EU Member States, with respect to the European Economic Area (EEA), and the U.K. General Data Protection Regulation (the U.K. GDPR, together with the EU GDPR the GDPR) and the U.K. Data Protection Act 2018 with respect to the United Kingdom (U.K.). These laws impose a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases or a condition for processing personal data relating to identifiable individuals and transferring such information outside the EEA or the U.K., providing details to those individuals regarding

the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the EEA and U.K. data protection regimes. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

The GDPR prohibits the international transfer of personal data to countries outside of the EEA or the U.K. ("third countries") which are not deemed as adequate for the transfers of personal data by competent authorities, unless a derogation exists or adequate safeguards (for example, the European Commission approved Standard Contractual Clauses ("EU SCCs") and the U.K. International Data Transfer Agreement/Addendum ("U.K. IDTA")) are implemented. Where relying on the EU SCCs or U.K. IDTA for data transfers, we may also be required to carry out transfer impact assessments on a case-by-case basis to ensure the law in the data importer's country and the data importer can ensure sufficient guarantees for safeguarding the personal data. These international transfer restrictions will require significant effort and cost and may result in us needing to make strategic considerations around storage and transfer of personal data.

The EU Commission has adopted its adequacy decision for the EU-U.S. Data Privacy Framework ("Framework") agreed with the U.S., which entered into force on July 11, 2023. This Framework provides a further avenue to transfer European personal data to U.S. companies which self-certified with the Framework, without the need for further safeguards. However, the Framework's validity has already been challenged in European courts and the Framework could subsequently be invalidated like its predecessors Privacy Shield and Safe Harbor frameworks.

Although the U.K. is regarded as a third country under the EU's GDPR, the European Commission has issued an adequacy decision recognizing the U.K. as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the U.K. remain unrestricted. In December 2025, the European Commission adopted a decision to extend the validity of the U.K. adequacy decision for six years until December 2031, determining that the U.K. continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the U.K.'s adoption of the Data (Use and Access) Act 2025 (the DUAA) on 19 June 2025. Like the EU GDPR, the U.K. GDPR restricts personal data transfers outside the U.K. to countries not regarded by the U.K. as providing adequate protection. The U.K. Government has confirmed that personal data transfers from the U.K. to the EEA remain free flowing. The respective provisions and enforcement of the EU GDPR and U.K. GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

The potential of the respective provisions and enforcement of the EU GDPR and U.K. GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future U.K. laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of European personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the U.K. and the EEA. In addition, EEA Member States have adopted national laws to implement the EU GDPR that may partially deviate from the EU GDPR and competent authorities in the EEA Member States may interpret the EU GDPR obligations slightly differently from country to country. Therefore, we do not expect to operate in a uniform legal landscape in Europe

If we are investigated by a European or U.K. data protection authority, we may face fines and other penalties, including bans on processing and transferring personal data. EEA and U.K. data protection authorities have the power to impose administrative fines for violations of the GDPR of up to a maximum of €20 (£17.5 under the U.K. GDPR) million or 4% of our total worldwide global turnover for the preceding fiscal year, whichever is higher, and violations of the GDPR may also lead to damages claims by data controllers and data subjects. Such penalties are in addition to any civil litigation claims by data controllers, clients, and data subjects. 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.

The use of new and evolving technologies, such as artificial intelligence (AI), in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

Artificial intelligence presents risks and challenges that can impact our business including by posing cybersecurity risks to our confidential information, proprietary information, and personal data.

We continue to build and integrate artificial intelligence (AI) into our offerings, including in our own development and implementation of AI through the adoption of commercially available tools. Our use of AI presents risks and challenges that could adversely affect our business and reputation, including cybersecurity, data privacy, IT, confidentiality, regulatory, legal, operational, competitive, reputational, intellectual property and other risks. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, bias and inequality, environmental and other harms may flow from our development or use of AI technologies. Certain AI tools may increase the risk of unauthorized disclosure of confidential information, compromise of proprietary intellectual property, or inadvertent inclusion of third-party intellectual property or other protected material, which could result in disputes or claims of infringement. Development, use, and deployment of these technologies could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational, and other risks and challenges that could affect our business. Specifically, risks related to bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks such as model poisoning or data poisoning, surveillance, data leakage, loss of consensus reality, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

Government and supranational regulation related to AI is evolving as new laws and regulations are implemented globally and could increase the burden and operational cost of compliance in this area, including through requirements related to transparency, accountability, risk management, human oversight, and data governance. We expect to see increasing regulation related to AI governance, use and ethics, which may also increase the burden and cost of research, development and compliance. For example, the EU's Artificial Intelligence Act (AI Act) entered into force on August 1, 2024, with important sections scheduled to come into effect in August 2026. As currently enacted, the AI Act imposes significant obligations on providers and deployers of high-risk AI systems and general purpose AI models, and encourages providers and deployers of AI systems to account for EU ethical principles when developing and using AI technology. The scope of requirements depends on legal and risk determinations that rely on legal provisions that have not yet been fully interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the current administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, there is continued uncertainty regarding the application of existing federal and state legal frameworks to uses and development of AI, and legal norms and market standards regarding AI continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U.S. Food and Drug Administration, for example, issued guidance on the use of AI in medical devices, requiring detailed risk management and

review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation, in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools. Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Even if we obtain FDA or EMA approval any of our product candidates in the U.S. or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the U.S. or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. In many jurisdictions outside the U.S., 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.

Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The U.S. 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. Additional changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the ACA and the passage of additional laws and regulations may

result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program. For more information regarding the risks related to recently enacted and future legislation please see "*Business — Government Regulation — Healthcare Reform Measures.*"

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act of 1977 (FCPA) and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA, U.S. domestic bribery statutes, and similar anti- bribery or anti-corruption laws, regulations or rules of other countries in which we may operate, including the

U.K. Bribery Act of 2010. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. There is no certainty that all of our employees, agents, contractors or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards, FCPA and similar anti-bribery and anti-corruption laws, and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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 these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of PMN310 or any other product candidate. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations. We may in the future operate beyond the United States and, if approved, we may sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Business and Industry

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 or more effective than ours.

The development and commercialization of new drugs is highly competitive. Moreover, the AD field is characterized by strong competition and a strong emphasis on intellectual property. We may face competition with respect to any 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.

If approved, PMN310 will likely compete with therapies currently approved for the treatment of patients with AD, which have primarily been developed to treat the symptoms of AD rather than the underlying cause of the disease, such as memantine and cholinesterase inhibitors. PMN310 may also compete with one or more potentially disease-modifying therapeutics that target Aβ or amyloid plaques. Biogen's aducanumab (Aduhelm) was approved by the FDA in June 2021 under the Accelerated approval pathway but commercialization was discontinued in January 2024. Lecanemab (Leqembi) from Eisai and Biogen received traditional approval from FDA in 2023, and donanemab (Kisunla) from Lilly received approval in 2024. Other companies known to be developing therapies with Aβ/amyloid plaque-related targets include Alzheon, Inc., Alzinova AB, Chugai Pharmaceutical Co. Ltd., Cognition Therapeutics, Inc., Eisai Co., Ltd., Eli Lilly and Company, Grifols, S.A., KalGene Pharmaceuticals, Inc., Neurimmune AG, Novartis AG, Acumen Pharmaceuticals Inc., Prothena Biosciences, Inc., Roche Holding AG (including Genentech, its wholly owned subsidiary) and Wren Therapeutics, Inc. Additionally, PMN310, if approved, may also compete with other potential therapies intended to address underlying causes of AD that are being developed by several companies, including AbbVie Inc., AC Immune SA, Alector, Inc., Anavex Life Sciences Corp., Annovis Bio, Inc., Athira Pharma, Inc., Biohaven Pharmaceuticals, Inc., Cassava Sciences, Inc., Cortexyme, Inc., Denali Therapeutics, Inc., Johnson & Johnson (including Janssen, its wholly-owned subsidiary) and Takeda Pharmaceutical Co. Ltd.

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, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved product candidates 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 product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop. Furthermore, currently approved product candidates could be discovered to have application for treatment of AD, which could give such product candidates 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 product candidates more rapidly than we may obtain approval for ours from the FDA, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, product candidates 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.

If our competitors market product candidates that are more effective, safer or less expensive than our product candidates, if approved, or that reach the market sooner than our product candidates, we may not achieve commercial success. In addition, the pharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or product candidates developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, particularly our CEO, Neil Warma, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates or any future product candidates.

Competition for qualified personnel in the biopharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

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

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.

Risks Related to Ownership of Our Common Shares and Our Status as a U.S. Public Company

Our Common Shares are currently listed on Nasdaq. We cannot assure you that we will be able to maintain a listing of our Common Shares on any such trading venue.

On January 8, 2025, we received written notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because, for the 30 consecutive business days prior to the date of the deficiency letter, the closing bid price for our Common Shares was trading below the minimum $1.00 per share requirement. We subsequently regained compliance as of December 12, 2025.

If Nasdaq delists our Common Shares, investors may face material adverse consequences, including, but not limited to, a lack of trading market for the Common Shares, reduced liquidity, decreased analyst coverage of the Company, and an inability for us to obtain additional financing to fund our operations. While a listing on an over-the-counter exchange could maintain some degree of a market in our Common Shares, we could face substantial material adverse consequences, including, but not limited to, the following: limited availability for market quotations for our Common Shares; reduced liquidity with respect to and decreased trading prices of our Common Shares; a determination that shares of our Common Shares are "penny stock" under the SEC rules, subjecting brokers trading our Common Shares to more stringent rules on disclosure and the class of investors to which the broker may sell the Common Shares; limited news and analyst coverage for our Company, in part due to the "penny stock" rules; decreased ability to issue additional securities or obtain additional financing in the future; and potential breaches under or terminations of our agreements with current or prospective large stockholders, strategic investors and banks. The perception among investors that we are at heightened risk of delisting could also negatively affect the market price of our securities and trading volume of our common stock.

Investment in the Company's Common Shares is speculative, involves risk, and there is no guarantee of a return.

There is no guarantee that the Common Shares will earn any positive return in the short term or long term. A holding of Common Shares is speculative and involves a high degree of risk and should be undertaken only by holders whose financial resources are sufficient to enable them to assume such risks and who have no need for immediate liquidity in their investment. A holding of Common Shares is appropriate only for holders who have the capacity to absorb a loss of some or all of their holdings.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our share price and trading volume could decline.

The trading market for our Common Shares will be influenced by the research and reports that equity research analysts publish about us and our business. As a relatively new public company, we anticipate having only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our Common Shares, and such lack of research coverage may adversely affect the market price of our Common Shares. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our

company or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause our shares price or trading volume to decline.

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

Based on their shareholdings as of December 31, 2025, our directors, executive officers and beneficial owners of greater than 5% of our outstanding shares and their respective affiliates will beneficially own, in the aggregate, approximately 60% of our outstanding Common Shares. As a result, these persons, acting together, would be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets or other significant corporate transactions.

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

Our constating documents permit us to issue an unlimited amount of additional Common Shares or Preferred Shares, which may prevent a third-party takeover or cause our shareholders to experience dilution in the future.

Our constating documents authorize us to issue an unlimited number of Common Shares and an unlimited number of Preferred Shares. Our Board has the authority to cause us to issue additional Common Shares and Preferred Shares and to determine the special rights and restrictions of the shares of one or more series of our Preferred Shares, each without consent of our shareholders. The issuance of any such securities may result in a reduction of the book value or market price of our Common Shares. Given the fact that we have not achieved profitability or generated positive cash flow historically, and we operate in a capital-intensive industry with significant working capital requirements, we may be required to issue additional Common Shares or other securities that are dilutive to existing shareholders in the future in order to continue our operations.

For example, on September 22, 2023, we filed a registration statement on Form S-3 (File No. 333-274658) with the SEC, which was declared effective on September 29, 2023 (2023 Shelf Registration Statement), in relation to the registration of Common Shares, preferred shares, subscription receipts, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our Common Shares, debt securities or other equity securities in one or more offerings. On January 5, 2024, we entered into an At The Market Offering Agreement with BTIG, LLC to provide for the offering, issuance and sale of up to an aggregate amount of $25.0 million of our Common Shares from time to time in "at-the-market" offerings under the 2023 Shelf Registration Statement and subject to the limitations thereof, including the rules applicable to us if our public float as of a measuring date preceding the Annual Report is less than $75 million. On July 21, 2025, the At The Market Offering Agreement was terminated.

On August 13, 2025, we filed a registration statement on Form S-3 (File No. 333-289577) with the SEC, which was declared effective on September 4, 2025 (2025 Shelf Registration Statement), in relation to the registration of Common Shares for the purposes of selling, from time to time, our Common Shares in one or more offerings. On August 13, 2025, we entered in an At The Market Offering Agreement with H.C. Wainwright & Co, LLC to provide for the offering, issuance, and sale of up to an aggregate amount of $18.0 million of our Common Shares from time to time in "at-the-market" offerings under the 2025 Shelf Registration Statement and subject to the limitations thereof, including the rules applicable to us if our public float as of a measuring date preceding the Annual Report is less than $75 million, which rules we are currently subject to. Sales of Common Shares, debt securities or other equity securities by us may represent a significant percentage of our Common Shares currently outstanding. If we sell, or the market perceives that we intend to sell, substantial amounts of our Common Shares under the 2025 Shelf Registration Statement or otherwise, the market price of our Common Shares could decline significantly.

Our efforts to fund our intended business plan may result in dilution to existing shareholders. Further, any such issuances could result in a change of control or a reduction in the market price for our Common Shares. Additionally, the rights of the holders of Common Shares will be subject to, and may be adversely affected by, the rights of holders of any Preferred

Shares that may be issued in the future. For example, Preferred Shares typically rank senior to Common Shares as to dividend rights, liquidation preference or both and may be convertible into Common Shares. Lastly, our ability to issue Preferred Shares could make it more difficult for a third-party to acquire a majority of our outstanding voting shares, particularly in the event we issue Preferred Shares with special voting rights, the effect of which may be to deprive our shareholders of a control premium that might otherwise be realized in connection with an acquisition of us.

Anti-takeover provisions in our governing documents and under Canadian Law could prevent or delay transactions that shareholders may favor.

Provisions of our governing documents and the OBCA may discourage, delay or prevent a merger or acquisition that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their Common Shares, and may also frustrate or prevent any attempt by shareholders to change the direction or management. For example, these provisions:

- require a 66 2/3% majority of shareholder votes cast in favor of a resolution to effect various amendments to the Articles of Incorporation of the Company, as amended (the "**articles**");
- require that in the event of shareholders of the Company vote via written resolution, that such resolution must be signed by all shareholders of the Company entitled to vote on that resolution;
- establish advance notice requirements for nominations for election to the Board at any annual or special meeting of shareholders of the Company; and
- Any transaction in which a third-party seeks to acquire our voting securities or equity securities that would result in the acquiror holding greater than 20% of the securities of that class may be governed by Multilateral Instrument 62-104—*Take-Over Bids and Issuer Bids* (the "**Takeover Bid Rules**") promulgated by the Canadian Securities Administrators.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation and these differences may make our Common Shares less attractive to investors.

We are incorporated under the provincial laws of Ontario, Canada, and, therefore, certain of the rights of holders of our shares are governed by Canadian law, including the provisions of the OBCA, and by our articles. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations and these differences may make our Common Shares less attractive to investors.

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 Shares may be less attractive to investors.

We are an "emerging growth company" as defined in 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 shareholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our Common Shares less attractive because we will rely on these exemptions. If some investors find our Common Shares less attractive as a result, there may be a less active trading market for our Common Shares and our share 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 the last day of the fiscal year (i) following the fifth anniversary of the filing of our Form 10 Registration Statement, (ii) in which we have total annual gross revenue of at least $1.235 billion, or (iii) in which we are deemed to be a large accelerated filer, which means the market value of our Common Shares that are held by non-affiliates exceeds $700 million as of the prior June 30th, and the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide herein may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our Common Shares less attractive as a result of these elections, which may result in a less active trading market for our Common Shares and higher volatility in our share price.

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 until the fiscal year following the determination that our voting and non-voting Common Shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting Common Shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

We have never paid dividends on our capital shares and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our Common Shares will likely depend on whether the price of our Common Shares increases.

We have never declared or paid any dividends on our Common Shares and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our Board. Accordingly, investors must rely on sales of their Common Shares after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

General Risk Factors

We 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 U.S., we incur significant additional legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, 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 continue 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.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

Public health crises, such as a pandemic, epidemic or outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and potential future commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

Public health crises, such as a pandemic, epidemic or outbreak of other highly infectious or contagious diseases, could adversely impact our business, the business operations of third parties on whom we rely and our ongoing or planned research and development activities. Additionally, timely enrollment in our ongoing and planned clinical trials is dependent upon clinical trial sites which may be adversely affected by global health concerns. Public health crises could result in increased adverse events and deaths in our clinical trials. Some factors from public health crises that could delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on public health crises, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials and the need for drugs and other supplies that clinical trial sites must have on hand to conduct our clinical trials to be used to address such public health crises;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;

- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and other supplies used in our prospective clinical trials;
- interruptions in operations at third-party manufacturers, which could result in delays or disruptions in the supply of our current product candidates and any future product candidates; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, product manufacturing and supply, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

The elimination of monetary liability against our directors, officers, and employees under Canadian law and the existence of indemnification rights for our obligations to our directors, officers, and employees may result in substantial expenditures by us and may discourage lawsuits against our directors, officers, and employees.

Our by-laws provide that, subject to the OBCA, we may indemnify a director or officer or a former director or officer or a corporation of which the we are or were a shareholder or creditor and their heirs and legal representatives of such person against all costs, charges, and expenses including and amount to be paid to settle an action or satisfy a judgment, reasonably incurred in respect of any civil, criminal or administrative action or proceeding to which they are made a party by reason of being or having been a director or officer of us or a director or officer of any such corporation. Each director and officer upon being elected and appointed shall be deemed to have contracted with us on the terms of this indemnity. The failure of a director or officer to comply with the provisions of the OBCA or the articles or the by-laws shall not invalidate any indemnity to which they are entitled under the by-laws.

We may also have contractual indemnification obligations under any future employment agreements with our officers or agreements entered into with our directors. The foregoing indemnification obligations could result in us incurring substantial expenditures to cover the cost of settlement or damage awards against directors and officers, which we may be unable to recoup. These provisions and the resulting costs may also discourage us from bringing a lawsuit against directors and officers for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our shareholders against our directors and officers even though such actions, if successful, might otherwise benefit us and our shareholders.

There may be difficulty in enforcing judgments and effecting service of process on directors and officers that are not citizens of the U.S.

We are incorporated under the OBCA and some of our directors and officers reside outside of the U.S., in Canada. Consequently, it may not be possible for an investor to effect service of process within the U.S. on us or those persons. Furthermore, it may not be possible for an investor to enforce judgments obtained in U.S. courts based upon the civil liability provisions of U.S. federal securities laws or other laws of the U.S. against us or those persons. There is doubt as to the enforceability, in original actions in Canadian courts, of liabilities based upon U.S. federal securities laws and as to the enforceability in Canadian courts of judgments of U.S. courts obtained in actions based upon the civil liability provisions of the U.S. federal securities laws. Therefore, it may not be possible to enforce those actions against us and certain of our directors and officers.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The rules dealing with federal, state and local income taxation are constantly under review by persons involved in the legislative process and, in the case of U.S. tax laws, by the Internal Revenue Service and the U.S. Treasury Department,

and in the case of Canadian tax laws, by the Canada Revenue Agency and the Department of Finance. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our Common Shares. For example, under Section 174 of the code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. are capitalized and amortized, which may have an adverse effect on our cash flow. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation.

Additional changes to U.S. federal income tax law are currently being contemplated, and future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. Since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. For example, on July 4, 2025, the One Big Beautiful Bill Act was signed into law and made significant changes to U.S. federal tax law. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

If we are characterized as a passive foreign investment company (PFIC), U.S. Holders may be subject to adverse U.S. federal income tax consequences.

Based on our current operations, income, assets and certain estimates and projections, including as to the relative values of our assets, including goodwill, which is based on the expected price of our Common Shares, we were not a PFIC for the 2024 taxable year and do not expect to have been a PFIC for the 2025 taxable year. [1]

However, we must make an annual determination as to whether we are a PFIC based on the types of income we earn and the types and value of our assets from time to time, all of which are subject to change. Therefore, we cannot assure you that we will not be a PFIC for our current taxable year or any future taxable year. A non-U.S. corporation generally will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The market value of our assets may be determined in large part by the market price of the Common Shares, which is likely to fluctuate. In addition, the composition of our income and assets will be affected by how, and how quickly, we use any cash that we raise. If we were to be treated as a PFIC for any taxable year during which you hold Common Shares, certain adverse U.S. federal income tax consequences could apply to U.S. Holders.

For purposes of this discussion, a "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of Common Shares, and who is: (i) an individual who is a citizen or individual resident of the U.S.; (ii) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the U.S., any state therein or the

[1] NTD: Please confirm that Company has not performed PFIC analysis for FY 2025, i.e., ensure that this sentence should not instead read "we were not a PFIC for the 2025 taxable year and do not expect to be a PFIC for the 2026 taxable year." If not, fine to leave as-is.

District of Columbia; (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or (iv) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election in effect to be treated as a U.S. person under applicable U.S. Treasury Regulations.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity posture or a natural disaster.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, we, like others in our industry, have experienced and expect to continue to experience cybersecurity incidents, data breaches, and similar threats related to our infrastructure. We, like other organizations, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, including via attachments to emails, the theft, fraud, and subsequent misuse of employee credentials, wrongful conduct by insider employees or vendors, denial-of-service attacks, attacks enhanced or facilitated by AI, ransomware attacks, business email compromises, breakdown, wrongful intrusions, data breaches, and social engineering (including phishing attacks). Attempts to disrupt or gain unauthorized access to our and our third-party service providers' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by AI. The risk of a security incident or breach or disruption, particularly through cyberattacks 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. 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, 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. To the extent that any disruption or security incident or breach was to result in a loss of or damage to our data or applications, systems, or infrastructure, or inappropriate disclosure or misuse of confidential or proprietary information, we could incur material legal claims and liability (including litigation and regulatory actions), financial costs, and damage to our reputation, and the further development of our product candidates could be delayed.

While we have not directly experienced any material system failure, accident or cybersecurity incident or breach to date, like others in our industry we and our vendors have, and may in the future continue to experience, threats and cybersecurity incidents relating and other attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems. We cannot guarantee that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, or cybersecurity incidents or breaches in or compromises of our systems or those of third-party CROs, vendors, contractors, consultants and/or third parties with whom we do business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

Additionally, the regulatory environment surrounding information security is increasingly demanding, with the frequent imposition of new and changing requirements. Compliance with changes in information security laws and with rapidly evolving industry standards may result in our incurring significant expense due to increased investment in technology and the development of new operational processes related to cybersecurity.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns 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 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 or biologics to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from October 1, 2025 to November 12, 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government 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.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our current or future clinical trials may be conducted outside of the U.S. and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from potential public health crises, weather catastrophe, acts of terrorism, war (such as the military conflict between Russia and Ukraine), threats of terrorist attacks or war, political disruption or other events outside of our control could result in a variety of risks to our business, including, among other things, weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Rising inflation rates may result in increased operating costs and reduced liquidity, and affect our ability to access credit.

Increased inflation may result in increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve System has repeatedly raised, and may continue to raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

Item 1B. Unresolved Staff Comments

None

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing risks to the security, confidentiality, integrity, and availability of our business systems and confidential information, including personal information and intellectual property. We have developed a cybersecurity risk management program in accordance with our risk profile and business. Leveraging the support of a third-party information technology provider, our cybersecurity risk management program includes cybersecurity awareness training for employees and periodic systems monitoring and vulnerability scanning.

We have not identified cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party vendors may from time to time experience threats that could affect our information or systems. For more information, please see the section entitled "Risk Factors" in this Annual Report on Form 10-K.

Governance Related to Cybersecurity Risks

Our Vice President, Finance and Chief Executive Officer, with the assistance of the Company's third-party information technology provider, are responsible for the strategic leadership and direction of the Company's cybersecurity program.

The Board exercises oversight of risks from cybersecurity threats primarily through its Audit Committee. Our Vice President, Finance, with input of other members of Company management and the Company's information technology provider, periodically makes presentations to the Audit Committee on the Company's enterprise risk management program, which may address cybersecurity risks and related cyber strategy, as applicable.

Item 2. Properties

The Company does not own or lease any material properties.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

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

Our Common Shares are listed on the Nasdaq Capital Market.

Shareholders

As of March 23, 2026 there were 152 holders of record of our Common Shares.

Dividends

There are no restrictions in our articles, by-laws or elsewhere which would prevent us from paying dividends. No dividends have been declared or paid on the Common Shares in the last five fiscal years, and it is not expected that dividends will be declared or paid in the immediate or foreseeable future. Consequently, to date there have been no distributions made by us.

The policy of our Board is to reinvest all available funds in operations. The Board will reassess this policy from time to time. Any decision to pay dividends on the Common Shares will be made by the Board based on the assessment of, among other factors, earnings, capital requirements and our operating and financial condition.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be set forth in the 2025 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" and is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Ownership and Exchange Controls

There is no limitation imposed by Canadian law or by our Constating Documents on the right of a non-resident to hold or vote our Common Shares.

Recent Sales of Unregistered Securities

The following information represents securities sold by us during the year ended December 31, 2025, and through the filing of this Annual Report on Form 10-K, which were not registered under the Securities Act. Included are new issues, securities issued in exchange for property, services or other securities and new securities resulting from the modification of outstanding securities. We sold all of the securities listed below pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act, or Regulation D or Regulation S promulgated thereunder.

- On April 4, 2025, we granted 3,800 Stock Options with an exercise price per Stock Option of $18 to certain directors, advisors, executives and employees. No consideration was received by us for this issuance.
- On June 12, 2025, we granted 4,000 Stock Options with an exercise price per Stock Option of $12.50 to certain directors, advisors, executives and employees. No consideration was received by us for this issuance.
- On July 22, 2025, we completed a PIPE Offering of 504,673 Common Share Warrant Units to Selling Shareholders for gross proceeds of approximately $2.4 million before deducting placement agent fees and other offering expenses. In conjunction with the proceeds from the exercise of existing warrants, the total gross proceeds inclusive of the PIPE Offering were approximately $9.2 million.
- On July 28, 2025, we completed a PIPE Offering of 624,654 PIPE Common Share Warrant Units to Selling Shareholders for gross proceeds of approximately $3.0 million before deducting placement agent fees and other offering expenses. In conjunction with the proceeds from the exercise of existing warrants, the total gross proceeds inclusive of the PIPE Offering were approximately $11.6 million.
- On September 22, 2025, we granted 47,600 Stock Options with an exercise price per Stock Option of $11.25 to certain directors, advisors, executives and employees. No consideration was received by us for this issuance.
- On January 30, 2026, we completed a PIPE Offering of an aggregate of approximately $75.5 million of (i) 6,815,296 Common Shares, no par value, (ii) Common Share Warrants to purchase 6,915,296 Common Shares or Pre-Funded Warrants in lieu thereof, and (iii) 100,000 Pre-Funded Warrants to purchase Common Shares before deducting placement agent fees and other offering expenses. There is an additional $100 million available tied to the exercise of the Common Share Warrants and Pre-Funded Warrants.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Material Canadian Federal Income Tax Considerations

The following is, as of the date hereof, a summary of the material Canadian federal income tax considerations generally applicable under the *Income Tax Act* (Canada) and the regulations promulgated thereunder, collectively the "Tax Act", to a purchaser who acquires as beneficial owner Common Shares under this offering, and who, for purposes of the Tax Act

and at all relevant times, (i) is not, and is not deemed to be, resident in Canada for purposes of the Tax Act and any applicable income tax convention, (ii) holds the common shares as capital property, (iii) deals at arm's length with, and is not affiliated with, the Company or the underwriters, and (iv) does not use or hold and will not be deemed to use or hold, the common shares in a business carried on in Canada, hereinafter a "Non-Resident Holder". Special rules, which are not discussed in this summary, may apply to a Non-Resident Holder that is an "authorized foreign bank" within the meaning of the Tax Act or an insurer carrying on an insurance business in Canada and elsewhere. Any such Non-Resident Holder should consult its own tax advisor.

This summary is based upon the provisions of the Tax Act in force as of the date hereof, all specific proposals to amend the Tax Act that have been publicly announced in writing by or on behalf of the Minister of Finance (Canada) prior to the date hereof, or the "Proposed Amendments", the Canada-U.S. Tax Treaty, or the "Treaty", and an understanding of the current administrative policies and assessing practices of the Canada Revenue Agency, or the "CRA", published in writing by it prior to the date hereof. This summary assumes the Proposed Amendments will be enacted in the form proposed. However, no assurance can be given that the Proposed Amendments will be enacted in their current form, or at all. This summary is not exhaustive of all possible Canadian federal income tax considerations and, except for the Proposed Amendments, does not take into account or anticipate any changes in the law or any changes in the CRA's administrative policies or assessing practices, whether by legislative, governmental or judicial action or decision, nor does it take into account or anticipate any other federal or any provincial, territorial or foreign tax considerations, which may differ significantly from those discussed herein.

This summary is not applicable to a Non-Resident Holder who reports its ''Canadian tax results'' in a currency other than Canadian currency; or that has entered or enters into a ''derivative forward agreement'' with respect to the common shares (each as defined in the Tax Act). Any such Non-Resident Holder should consult its own tax advisor with respect to an investment in the common shares.

This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice to any prospective purchaser or holder of the common shares, and no representations with respect to the income tax consequences to any prospective purchaser or holder are made. Consequently, prospective purchasers or holders of the common shares should consult their own tax advisors with respect to their particular circumstances.

Currency Conversion

Generally, for purposes of the Tax Act, all amounts relating to the acquisition, holding or disposition of the common shares must be converted into Canadian dollars based on the exchange rates as determined in accordance with the Tax Act. The amounts subject to withholding tax and any capital gains or capital losses realized by a Non-Resident Holder may be affected by fluctuations in the applicable exchange rate (such as the Canadian-U.S. dollar exchange rate).

Dividends

Dividends paid or credited or deemed to be paid or credited on the Common Shares to a Non-Resident Holder by the Company will be subject to Canadian withholding tax under the Tax Act at the rate of 25%, subject to any reduction under the provisions of an applicable income tax convention. For example, under the Treaty, the rate of withholding tax on dividends paid or credited or deemed to be paid or credited to a beneficially entitled Non-Resident Holder who is resident in the U.S. for purposes of the Treaty and who is fully entitled to the benefits of the Treaty is generally limited to 15% of the gross amount of the dividend. Non-Resident Holders are urged to consult their own tax advisors to determine their entitlement to relief under an applicable income tax treaty.

Dispositions

A Non-Resident Holder generally will not be subject to tax under the Tax Act in respect of a capital gain realized on the disposition or deemed disposition of a Common Share, unless the Common Share constitutes ''taxable Canadian property'' (as defined in the Tax Act) of the Non-Resident Holder at the time of disposition and the Non-Resident Holder is not entitled to relief under an applicable income tax convention.

Generally, the Common Shares will not constitute taxable Canadian property of a Non-Resident Holder at a particular time provided the common shares are listed at that time on a ''designated stock exchange,'' as defined in the Tax Act (which

currently includes the Nasdaq Stock Market), unless at any time during the 60-month period that ends at that time the following two conditions are satisfied concurrently: (i) (a) the Non-Resident Holder; (b) persons with whom the Non-Resident Holder did not deal at arm's length; (c) partnerships in which the Non-Resident Holder or a person described in (b) holds a membership interest directly or indirectly through one or more partnerships; or (d) any combination of the persons and partnerships described in (a) through (c), owned 25% or more of the issued shares of any class or series of the shares of the company; and (ii) more than 50% of the fair market value of the common shares was derived directly or indirectly from one or any combination of: (a) real or immovable property situated in Canada, (b) ''Canadian resource properties'', (c) ''timber resource properties'' (each as defined in the Tax Act), and (d) options in respect of, or interests in or for civil law rights in, such properties, whether or not such properties exist. Notwithstanding the foregoing, in certain circumstances set out in the Tax Act, the common shares could be deemed to be taxable Canadian property.

A Non-Resident Holder contemplating a disposition of Common Shares that may constitute taxable Canadian property should consult a tax advisor prior to such disposition.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*All references in this management's discussion and analysis of financial condition and results of operations, or MD&A, to the "Company", "ProMIS", "we", "us", or "our" refer to ProMIS Neurosciences Inc., unless otherwise indicated or the context requires otherwise. The following MD&A is prepared as of March 25, 2026 for the years ended December 31, 2025 and 2024 and should be read in conjunction with the audited consolidated financial statements for the years ended December 31, 2025 and 2024 (collectively, the "**Financial Statements**"), which have been prepared by management in accordance with United States generally accepted accounting principles ("**U.S. GAAP**") as issued by the Financial Accounting Standards Board ("**FASB**"). All dollar amounts refer to United States dollars, except as stated otherwise.*

Overview

We are applying our patented technology platform to build a portfolio of antibody therapies and therapeutic vaccines in neurodegenerative diseases and other protein-misfolding diseases, with a focus on Alzheimer's disease (AD), multiple system atrophy (MSA), and amyotrophic lateral sclerosis (ALS). We believe these diseases share a common biologic cause — misfolded versions of proteins, that otherwise perform a normal function, becoming toxic and killing neurons, resulting in disease. ProMIS' technology platform enables drug discovery through a combination of protein biology, physics and supercomputing. We believe this platform provides a potential advantage in selectively targeting the toxic misfolded proteins with therapeutics or detecting them with diagnostics.

We are developing a pipeline of antibodies aimed at selectively targeting misfolded toxic forms of proteins that drive neurodegenerative diseases without interfering with the essential functions of the same properly folded proteins. Our product candidates are PMN310, PMN267, and PMN442. Our lead product candidate is PMN310, a monoclonal antibody designed to treat AD by selectively targeting toxic, misfolded oligomers of amyloid-beta. PMN267 is our second lead product candidate targeting ALS. It has been shown in preclinical studies to selectively recognize misfolded, cytoplasmic TDP-43 aggregates without interacting with normal TDP-43. Misfolded TDP-43 is believed to play an important role in the development of ALS. In light of research suggesting that misfolded toxic a-syn is a primary driver of disease in synucleinopathies such as MSA and Parkinson's disease, our third lead product candidate, PMN442 has shown robust binding to pathogenic a-syn oligomers and seeding fibrils in preclinical studies, with negligible binding to a-syn monomers and physiologic tetramers which are required for normal neuronal function. We also have earlier stage preclinical programs and a project to refine our discovery algorithm using machine learning as highlighted in the "Other Key Projects" section below.

We were incorporated on January 23, 2004 under the Canada Business Corporations Act (CBCA). On July 13, 2023, we continued our existence from a corporation incorporated under the CBCA into the Province of Ontario under the Business Corporations Act (Ontario) (OBCA) (Continuance). The Continuance was approved by our shareholders at our 2023 Annual Meeting of Shareholders held on June 29, 2023. We have a wholly-owned U.S. subsidiary, ProMIS USA, which was incorporated in January 2016 in the State of Delaware. ProMIS USA has had no material activity and has no material financial impact on our Financial Statements. Since our inception, we have devoted substantially all of our resources to developing our platform technologies and the resultant antibody product candidates, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We have principally financed our operations through public and private placements of Common Shares and warrants and convertible debt.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product candidates and any future product candidates. We had an operating loss of $40.2 million and $16.8 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $130.4 million. We had negative cash flows from operations of $28.1 million for the year ended December 31, 2025. In July 2025, we received gross proceeds of $21.6 million from discounted warrant exercises, the sale of additional warrants in private placements, and the sale of pre-funded warrants to purchase Common Shares in a registered direct offering, less transaction costs of $1.4 million. Refer to additional discussion in Note 6.

In January 2026, we received gross proceeds of $75.5 million from the sale of Common Shares, Common Share warrants, and pre-funded warrants to purchase Common Shares to external investors and certain of our directors and management in a private placement. Fees and other expenses are currently not estimable, as they are still being determined. Refer to additional discussion in Note 14.

Based on our current operating plan, we expect that our existing cash, including the proceeds from January 2026, will be sufficient to fund our operating expenses and capital expenditure requirements through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, including based on our decision to initiate other clinical trials or programs.

However, we expect to continue to incur losses for the foreseeable future and, if able to raise additional funding, would expect our research and development expenses, general and administrative expenses and capital expenditures to increase. In particular, if we are able to raise additional funding we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as continue and initiate new clinical trials, hire additional personnel, and pay fees to outside consultants, lawyers and accountants. In addition, if we obtain marketing approval for any product candidates, we may incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, our "at-the-market" program, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Components of Operating Results

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of our products in the near future, if at all. If our product candidates are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development and research of our platform technologies, as well as unrelated discovery program expenses. We expense research and development costs in the periods in which they are incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and share-based compensation expense, for employees engaged in research and development activities;

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations (CROs), and consultants;
- the cost of acquiring, developing, and manufacturing clinical study materials; and
- costs associated with clinical and preclinical activities and regulatory operations.

We enter into consulting, research, and other agreements with commercial entities, researchers, universities, and others for the provision of goods and services. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the respective vendors, including our clinical sites. These costs consist of direct and indirect costs associated with our platform technologies, as well as fees paid to various entities that perform certain research on our behalf. Depending upon the timing of payments to the service providers, we recognize prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. We monitor each of these factors and adjust estimates accordingly. See Item 1A -*"Risk Factors*" in this document.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to implement our business strategy, which includes advancing our platform technologies through clinical development as well as other product candidates into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research efforts, our clinical and product development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials.

We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Our direct research and development expenses consist primarily of external costs, including fees paid to consultants, contractors and CROs in connection with our development activities and the cost of acquiring, developing, and manufacturing clinical study materials.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs including salary, bonus, employee-benefits and share-based compensation, costs incurred in development and protection of intellectual property, professional service fees, and other general overhead and facility costs, depreciation, and amortization. We expect our general and administrative expenses to increase substantially for the foreseeable future as we increase our administrative function to support the growth of the business and its continued clinical development activities.

Other Income (Expense)

Other expenses consist primarily of interest expense on certain deferred accounts payable and the loss on issuance of common shares, warrants and pre-funded warrants in the July 2024 Private Placement. Other income consists of changes in the fair value of our warrant liabilities and interest income earned on our cash balances.

Result of Operations

Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years presented:

	Years Ended December 31, 2025	2024	Change
Operating expenses			
Research and development	$ 33,379,321	$ 10,637,976	$ 22,741,345
General and administrative	6,787,987	6,189,502	598,485
Total operating expenses	40,167,308	16,827,478	23,339,830
Loss from operations	(40,167,308)	(16,827,478)	23,339,830
Other income	448,161	19,606,351	19,158,190
Net (loss) income	$ (39,719,147)	$ 2,778,873	$ 42,498,020

Research and Development Expenses

The following table summarizes the year-over-year changes in research and development expenses for the years presented:

	Years Ended December 31, 2025	2024	Change
Direct research and development expenses by program			
PMN310	$ 30,226,059	$ 8,275,268	$ 21,950,791
ALS	—	7,850	(7,850)
Platform and other programs	685,113	632,003	53,110
Indirect research and development expenses:			
Employee salaries and benefits	2,100,417	1,540,802	559,615
Share-based compensation	166,938	49,405	117,533
Consulting expense	149,083	66,021	83,062
Other operating costs	51,711	66,627	(14,916)
Total research and development expenses	$ 33,379,321	$ 10,637,976	$ 22,741,345

Research and development expenses increased by $22.7 million, or 214%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase is primarily attributable to a $22.0 million increase in spending on our lead program, PMN310, as our Phase 1b clinical trial of PMN 310, which began in late 2024, continued to progress. Employee salaries and benefits also increased by $0.6 million as we hired additional personnel in 2025 to support the Phase 1b study. Consulting expenses increased by $0.1 million while other operating costs remained consistent during the year ended December 31, 2025 compared to the year ended December 31, 2024.

General and Administrative Expenses

The following table summarizes the year-over-year changes in general and administrative expenses for the years presented:

	Years Ended December 31, 2025	2024	Change
Employee salaries and benefits	$ 2,093,231	$ 969,970	$ 1,123,261
Share-based compensation	690,691	776,403	(85,712)
Professional and consulting fees	3,291,976	3,985,899	(693,923)
Patent expense	286,265	304,600	(18,335)
Facility-related and other	425,824	152,630	273,194
Total general and administrative expenses	$ 6,787,987	$ 6,189,502	$ 598,485

General and administrative expenses increased by $0.6 million, or 10%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. Employee salaries and benefits increased by $1.1 million, primarily due to the recognition of $0.5 million in severance costs in 2025 and the hiring of additional employees in 2025. The $0.7 million decrease in professional and consulting costs included a $0.3 million decrease in external investor and shareholder relations, a $0.2 million decrease in legal fees, and a $0.2 million decrease in insurance costs. Facility-related and other costs increased by $0.3 million due to higher business development, internal investor relations, and conference activity in 2025. Share-based compensation costs decreased by $0.1 million and patent fees stayed consistent.

Other Income (Expense)

Other income (expense) decreased by $19.2 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily attributable to a decrease in gain on change in fair value of financial instruments of $22.6 million in 2025, which was driven in 2024 by the gain on the change in the July 2024 Private Placement warrant liability, a decrease of $0.2 million in interest income due to higher average cash balances and interest rates during the year ended December 31, 2024, and a decrease of $0.1 million in interest expense, offset by a $3.5 million one-time loss in 2024 on the issuance of common shares, warrants, and pre-funded warrants in issued in the July 2024 Private Placement.

Liquidity and Capital Resources

Sources of Liquidity

We are a clinical-stage development company as we have not generated any product revenues to date and do not expect to have significant revenues until we are able to sell a product candidate after obtaining applicable regulatory approvals or we establish collaborations that provide funding, such as licensing fees, milestone payments, royalties, research funding or otherwise. Operations have been financed since inception through the sale of equity and debt securities and the conversion of common share purchase warrants and share options. Our objectives, when managing capital, are to ensure there are sufficient funds available to carry out our research, development and eventual commercialization programs. When we have excess funds, we manage our liquidity risk by investing in highly liquid corporate and government bonds with staggered maturities to provide regular cash flow for current operations. We do not hold any asset-backed commercial paper and our cash is not subject to any external restrictions. We also manage liquidity risk by frequently monitoring actual and projected cash flows. The Board reviews and approves the Company's operating and capital budgets, as well as any material transactions not in the ordinary course of business. The majority of our accounts payable and accrued liabilities have maturities of less than three months. We are dependent on our ability to generate revenues from our future products or secure additional financing in order to continue our research and development activities and meet our ongoing obligations.

ATM Agreements

In September 22, 2023, we filed a registration statement on Form S-3 with the SEC, which was declared effective on September 29, 2023 (Shelf Registration Statement), in relation to the registration of Common Shares, preferred shares, subscription receipts, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our Common Shares, debt securities or other equity securities in one or more offerings. In January 2024, we entered into an At The Market Offering Agreement with BTIG, LLC (2024 ATM Agreement) to provide for the offering, issuance and sale of up to an aggregate amount of $25.0 million of our Common Shares from time to time in "at-the-market" offerings under the Shelf Registration Statement and subject to the limitations thereof, including limitations related to the amount we are able to sell pursuant to such ATM Program based on our public float as of a measuring date preceding the filing of our Annual Report. During the year ended December 31, 2024 we sold 3,034 shares for net proceeds of approximately $0.2 million, after deducting sales commissions. We did not sell any Common Shares in 2025 pursuant to the 2024 ATM Agreement and the 2024 ATM Agreement was terminated in July 2025.

In August 2025, we filed a new shelf registration statement with the SEC. In conjunction with the shelf registration, we entered into an At The Market Offering Agreement with H.C. Wainwright & Co., LLC (2025 ATM Agreement) to offer

up to $18.0 million of our Common Shares. During the year ended December 31, 2025, we sold 40,795 Common Shares for net proceeds of $0.7 million, after deducting sales commissions.

Financing Transactions

July 2024 Private Placement

In July 2024, we completed a private placement for aggregate gross proceeds of $30.3 million to sell an aggregate of (a) 390,307 common share units (Common Share Units) sold at $2.15 per Common Share Unit, each consisting of one Common Share and certain accompanying warrants to purchase Common Shares (Tranche A, B and C) and, for certain investors, (b) 174,841 pre-funded units (the Pre-Funded Units and together with the Common Share Units, the Units) sold at $2.14 per Pre-Funded Unit, each consisting of one pre-funded warrant to purchase one Common Share and certain accompanying warrants to purchase Common Shares (Tranche A, B and C), totaling 565,148 each of Tranche A, B and C warrants (July 2024 PIPE). The Common Shares issuable upon exercise of the warrants and pre-funded warrants are referred to herein as the "2024 Warrant Shares."

The pre-funded warrants have an exercise price of $0.25 per 2024 Warrant Share, are immediately exercisable and will expire when exercised in full. The Tranche A Common Share purchase warrants have an exercise price of $50.50, are exercisable immediately upon Shareholder Approval (as defined below) and will expire upon the earlier of (i) 18 months or (ii) within 60 days of the public announcement via press release or the filing of a Current Report on Form 8-K of 6-month data from the cohorts treated with multiple ascending doses of PMN310. The Tranche B Common Share purchase warrants have an exercise price of $50.50, are exercisable immediately upon Shareholder Approval (as defined below) and will expire upon the earlier of (i) 30 months or (ii) within 60 days of the public announcement via press release or the filing of a Current Report on Form 8-K of 12-month data from the cohorts treated with multiple ascending doses of PMN310. The Tranche C Common Share purchase warrants have an exercise price of $62.50, are immediately exercisable and will expire on July 31, 2029. Pursuant to Nasdaq Listing Rule 5635(d), the exercise of the Tranche A and Tranche B Common Share purchase warrants is subject to shareholder approval (Shareholder Approval). We received Shareholder Approval for the Tranche A and Tranche B warrants on October 23, 2024 at a Special Meeting of Shareholders.

July 2025 Registered Direct Offering

On July 22, 2025, we entered into a securities purchase agreement to issue and sell pre-funded warrants to purchase 39,389 Common Shares (RD Offering). The RD Offering pre-funded warrant was sold at an offering price of $0.8124 per share, which represents, if it were applicable, the per share offering price for the Common Shares of the Company, less a $0.0001 per share exercise price for such pre-funded warrant. The gross proceeds from the RD Offering were $0.8 million before deducting offering expenses of $0.1 million.

July 2025 Discounted Exercise of Warrants and Private Placements

Additionally, in July 2025, across multiple transactions dated July 22 and 28, 2025, we accepted discounted exercise offers for 752,885 Common Share warrants, distributed ratably amongst the Tranche A, B, and C warrants from the July 2024 PIPE for aggregate gross proceeds of approximately $15.5 million (Discounted Exercise) and sold 1,129,327 new warrants in two private placements for aggregate gross proceeds of $5.3 million (July 22, 2025 PIPE and July 28, 2025 PIPE). The total aggregate gross proceeds across the RD Offering, discounted warrant exercises, and sales of new warrants was $21.6 million, before deducting fees and offering expenses of $1.4 million.

January 2026 Private Placement

On January 29, 2026, we completed a private placement for aggregate gross proceeds of $75.5 million to sell an aggregate of (i) 6,815,296 Common Shares, (ii) Common Share purchase warrants (Common Share Warrants) to purchase 6,915,296 Common Shares, (iii) Pre-Funded Warrants (Pre-Funded Warrants) to purchase 100,000 Common Shares (January 2026 PIPE). The Common Shares issuable upon exercise of the Common Share Warrants and Pre-Funded Warrants are referred to herein as the "2026 Warrant Shares".

6,090,075 Common Shares were sold at a price of $10.77 per Common Share, 100,000 Pre-Funded Warrants were sold at a price of $10.77 less an exercise price $0.0001 per 2026 Warrant Share and 725,221 Common Shares were sold at a price of $12.13 per Common Share. The Common Share Warrants have an exercise price of $14.40, are exercisable immediately and will expire upon the earlier of (i) within 60 days of the Milestone Event (as defined below) or (ii) February 3, 2031. The Pre-Funded Warrants have an exercise price of $14.40 per 2026 Warrant Share, are immediately exercisable and will expire when exercised in full. For purposes of the foregoing, the "Milestone Event" means the public announcement via press release or the filing of a Current Report on Form 8-K of topline data from the cohorts treated with single ascending doses of PMN310. Fees and other expenses are currently not estimable by the Company, as they are still being determined.

Current Capital Position

We incurred an operating loss of $40.2 million in the year ended December 31, 2025, had an accumulated deficit of $130.4 million as of December 31, 2025, had negative cash flows from operations of $28.1 million for the year ended December 31, 2025 and finished the year ended December 31, 2025 with negative working capital of $1.2 million.

However, following the closing of the January 2026 Private Placement for gross proceeds of $75.5 million, and based on our current operating plan, we expect that our existing cash will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, including based on our decision to initiate other clinical trials or programs.

Additional funding will be necessary to fund future clinical activities. We will seek additional funding through public and private financings, debt financings, collaboration agreements, strategic alliances and licensing agreements. Although we have been successful in raising capital in the past, there is no assurance of success in obtaining such additional financing on terms acceptable to us, if at all, and there is no assurance that we will be able to enter into collaborations or other arrangements. If we are unable to obtain funding, it could force us to delay, reduce or eliminate research and development programs and product portfolio expansion or commercialization efforts. These potential delays, reductions and eliminations could adversely affect future business prospects, and the ability to continue operations.

Cash Flows

The following table summarizes our sources and uses of cash for the periods presented:

	Years Ended December 31,		
	2025	2024	Change
Net cash used in operating activities	$ (28,118,579)	$ (27,182,095)	$ (936,484)
Net cash used in investing activities	(702)	(693)	(9)
Net cash provided by financing activities	20,944,670	27,875,809	(6,931,139)
Net (decrease) increase in cash	$ (7,174,611)	$ 693,021	$ (7,867,632)

Cash Flows from Operating Activities

Cash used in operating activities was $28.1 million for the year ended December 31, 2025, which consisted of a net loss of $39.7 million offset by $0.9 million in non-cash charges and a net change of $10.7 million in our net operating assets and liabilities. The additive non-cash activities primarily consisted of non-cash charges for share-based compensation of $0.9 million. Changes in cash flows related to operating assets and liabilities primarily consisted of a $7.4 million in accrued liabilities and a $2.6 million increase in prepaid expenses and other current assets, primarily related to the PMN310 Phase 1b clinical trial.

Cash used in operating activities was $27.2 million for the year ended December 31, 2024, which consisted of net income of $2.8 million offset by $18.2 million in non-cash charges and a net change of $11.7 million in our net operating assets and liabilities. The additive non-cash activities primarily consisted of a gain on the change in fair value of financial instruments of $22.6 million, offset by non-cash charges for share-based compensation of $0.8 million and a $3.5 million loss on the issuance of common shares, warrants, and pre-funded warrants in the July 2024 Private Placement. Changes in cash flows related to operating assets and liabilities primarily consisted of a decrease of $6.1 million of accounts payable, a decrease of $1.0 million in accrued liabilities and a $4.6 million increase in prepaid expenses and other current assets, primarily related to the PMN310 Phase 1b clinical trial.

Cash Flows from Investing Activities

Cash used in investing activities was nominal during the years ended December 31, 2025 and 2024.

Cash Flows from Financing Activities

Cash provided by financing activities during the year ended December 31, 2025, was $20.9 million, which included $8.4 million from the July 22, 2025 Discounted Exercise (as detailed in our notes to the financial statements) and July 22, 2025 PIPE, $11.1 million from the July 28, 2025 Discounted Exercise (as detailed in our notes to the financial statements) and July 28, 2025 PIPE, $0.7 million from the sale of Common Shares under the 2025 At The Market Offering Agreement, and $0.7 million from the issuance of pre-funded warrants in the July 22, 2025 RD Offering.

Cash provided by financing activities during the year ended December 31, 2024 was $27.9 million which included $27.7 million from the common shares, pre-funded warrants, and common share warrants sold in the July 2024 PIPE and $0.2 million of proceeds from the sale of common shares from the 2024 ATM offering.

Critical Accounting Policies and Estimates

Our MD&A is based on our Financial Statements, which have been prepared in accordance with U.S. GAAP and on a basis consistent with those accounting principles followed by us and disclosed in Note 2 to our audited consolidated financial statements for the year ended December 31, 2025. The preparation of these Financial Statements in conformity with U.S. GAAP requires our management to make certain judgments and estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the Financial Statements, as well as the reported 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 judgement about the carrying value of assets and liabilities that are not readily apparent from other sources. Significant estimates and judgments include, but are not limited to, accruals for research and development expenses. Accordingly, actual results may differ from these judgments and estimates under different assumptions or conditions and any such difference may be material.

We believe that the following critical accounting estimates discussed below are most important to understanding our historical and future performance, as these estimates relate to the more significant areas involving management’s judgments and estimates.

Accruals for Research and Development Expenses

Substantial portions of the Company's clinical and preclinical trials and drug substance manufacturing are performed by third-party laboratories, medical centers, and other vendors. These vendors generally bill monthly for services performed, or bill based upon milestone achievement. For clinical and preclinical studies, the Company recognizes and, if necessary, accrues expenses based upon estimated percentage of work completed and the remaining contract milestones. The Company estimates the period over which such services will be performed based on the terms of the agreements as well as the level of effort to be expended in each period. Sometimes the actual timing of performance or the level of effort varies from the estimate, and if that does occur, the Company will adjust the amounts recorded accordingly.

The percentage of work completed is inherently subject to estimation uncertainty, and the Company uses third-party invoices, contract terms, and support provided directly from third parties, when available, to establish the percentage of completion at each measurement date. A hypothetical difference in estimated percentage of work completed compared to actual percentage of work completed of 10% for a $1.0 million contract at the measurement date could have a $0.1 million impact on accrued liabilities and research and development expenses. The Company had $7.4 million of accrued research and development costs and $2.6 million of prepaid upfront research payments, which had not yet been recognized at December 31, 2025, and which are from multiple contracts.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited consolidated financial statements in Item 8 – "*Financial Statements and Supplementary Data*".

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of business, we are exposed to a number of financial risks that can affect our operating performance. These risks are credit risk, liquidity risk and market risk. Our overall risk management program and prudent business practices seek to minimize any potential adverse effects on our financial performance.

Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and short-term investments. We manage our exposure to credit losses by placing our cash with accredited financial institutions, which at times, may exceed federally insured limits, and when we have excess funds, such funds are invested in high-quality government and corporate issuers with low credit risk. Cash held is not subject to any external restrictions. As of the year ended December 31, 2025, a hypothetical 10% relative change in interest rates would not have a material impact on our Financial Statements.

Liquidity Risk

Our exposure to liquidity risk is dependent on purchasing obligations and raising funds to meet commitments and sustain operations. We are a pre-revenue clinical-stage development company, and we rely on external fundraising to support our operations. We also manage liquidity risk by continuously monitoring actual and projected cash flows. Our Board reviews and approves the Company's operating budget, as well as any material transaction.

Foreign Currency Exchange Risk

We are exposed to foreign exchange risk on our non-U.S. dollar denominated cash and non-U.S. dollar denominated liabilities. We do not believe that foreign exchange impacts had a material effect on our business, financial condition or results of operations during the years ended December 31, 2025 or 2024.

Inflation Risk

Inflation generally affects us by increasing our cost of labor, outside consultants and CROs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2025 or 2024.

Item 8. Financial Statements and Supplementary Data

PROMIS NEUROSCIENCES INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
ProMIS Neurosciences Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ProMIS Neurosciences Inc. and Subsidiary (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, shareholders' (deficit) equity 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 consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated 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 audit 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.

/s/ Baker Tilly US, LLP

Tewksbury, Massachusetts
March 25, 2026

We have served as the Company's auditor since 2021.

PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

(expressed in U.S. dollars, except share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash	$ 6,116,556	$ 13,291,167
Short-term investments	33,753	33,051
Prepaid expenses and other current assets	3,032,112	5,587,238
Total current assets	9,182,421	18,911,456
Total assets	$ 9,182,421	$ 18,911,456
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 2,543,415	$ 1,737,463
Accrued liabilities	7,868,416	480,962
Total current liabilities	10,411,831	2,218,425
Share-based compensation liability	29,182	199,263
Warrant liability	—	5,592
Total liabilities	10,441,013	2,423,280
Commitments and contingencies		
Shareholders' (deficit) equity:		
Common Shares, no par value, unlimited shares authorized, 2,152,397 and 1,307,520 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	129,518,812	107,546,433
Accumulated other comprehensive loss	(371,184)	(371,184)
Accumulated deficit	(130,406,220)	(90,687,073)
Total shareholders' (deficit) equity	(1,258,592)	16,488,176
Total liabilities and shareholders' (deficit) equity	$ 9,182,421	$ 18,911,456

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

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations

(expressed in U.S. dollars, except share amounts)

	Years Ended December 31, 2025	2024
Operating expenses:		
Research and development	$ 33,379,321	$ 10,637,976
General and administrative	6,787,987	6,189,502
Total operating expenses	40,167,308	16,827,478
Loss from operations	(40,167,308)	(16,827,478)
Other income (expense):		
Change in fair value of financial instruments	5,592	22,581,477
Interest expense	—	(76,775)
Other income	442,569	626,184
Loss on issuance of Common Shares, warrants, and pre-funded warrants in July 2024 PIPE	—	(3,524,535)
Total other income, net	448,161	19,606,351
Net (loss) income	$ (39,719,147)	$ 2,778,873
Net (loss) income per share, basic	$ (22.61)	$ 2.68
Net (loss) income per share, diluted	$ (22.61)	$ 2.63
Weighted-average outstanding Common Shares, basic	1,756,844	1,036,799
Weighted-average outstanding Common Shares, diluted	1,756,844	1,058,469

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

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Shareholders' (Deficit) Equity

(expressed in U.S. dollars, except share amounts)

	Series 2 Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, January 1, 2024	46,667	—	755,362	—	97,590,426	(371,184)	(93,465,946)	3,753,296
Share-based compensation	—	—	—	—	825,808	—		825,808
Conversion of Series 2 Convertible Preferred Shares	(46,667)	—	46,667	—	—	—	—	—
Issuance of Common Shares from 2024 ATM Offering, net of issuance costs	—	—	3,034	—	190,274	—	—	190,274
Issuance of Common Shares, pre-funded warrants and accompanying Common Share warrants in July 2024 PIPE, net of issuance costs	—	—	390,307	—	—	—	—	—
Reclassification of July 2024 PIPE warrant liability to additional paid-in capital	—	—	—	—	8,689,148	—	—	8,689,148
Re-measurement of liability-classified CAD stock options as of December 31, 2024	—	—	—	—	222,739	—	—	222,739
Issuance of Common Shares from exercise of pre-funded warrants	—	—	112,150	—	28,038	—	—	28,038
Net income	—	—	—	—	—	—	2,778,873	2,778,873
Balance, December 31, 2024	—	—	1,307,520	—	107,546,433	(371,184)	(90,687,073)	16,488,176
Share-based compensation	—	—	—	—	857,628	—	—	857,628
Issuance of Common Shares from 2025 ATM Offering, net of issuance costs	—	—	40,795	—	708,468	—	—	708,468
Issuance of pre-funded warrants from July 2025 Registered Direct Offering, net of issuance costs	—	—	—	—	697,658	—	—	697,658
Issuance of Common Shares from exercise of pre-funded warrants	—	—	51,197	—	3,050	—	—	3,050
Proceeds from issuance of Common Shares and warrants from July 22, 2025 discounted warrant exercise and PIPE, net of issuance costs	—	—	336,449	—	8,391,027	—	—	8,391,027
Proceeds from issuance of Common Shares and warrants from July 28, 2025 discounted warrant exercise and PIPE, net of issuance costs	—	—	416,436	—	11,144,467	—	—	11,144,467
Re-measurement of liability-classified CAD stock options as of December 31, 2025	—	—	—	—	170,081	—	—	170,081
Net loss	—	—	—	—	—	—	(39,719,147)	(39,719,147)
Balance, December 31, 2025	—	$ —	2,152,397	$ —	$ 129,518,812	$ (371,184)	$ (130,406,220)	$ (1,258,592)

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

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Cash Flows

(expressed in U.S. dollars)

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net (loss) income	$ (39,719,147)	$ 2,778,873
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Share-based compensation expense	857,628	825,808
Loss on issuance of common shares, warrants, and pre-funded warrants in July 26, 2024 PIPE	—	3,524,535
Change in fair value of financial instruments	(5,592)	(22,581,477)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,555,126	(4,598,597)
Accounts payable	805,952	(6,105,673)
Accrued liabilities	7,387,454	(1,025,564)
Net cash used in operating activities	(28,118,579)	(27,182,095)
Cash flows from investing activities		
Purchase of short-term investments	(33,753)	(33,051)
Maturity of short-term investment	33,051	32,358
Net cash used in investing activities	(702)	(693)
Cash flows from financing activities		
Proceeds from issuance of Common Shares pursuant to 2025 and 2024 ATM offering, respectively, net of issuance costs	708,468	190,274
Proceeds from issuance of pre-funded warrants from July 22, 2025 Registered Direct Offering, net of issuance costs	697,658	
Proceeds from issuance of Common Shares and warrants from July 22, 2025 discounted warrant exercise and PIPE, net of issuance costs	8,391,027	—
Proceeds from issuance of Common Shares and warrants from July 28, 2025 discounted warrant exercise and PIPE, net of issuance costs	11,144,467	—
Proceeds from issuance of Common Shares, pre-funded warrants, and accompanying warrants from July 26, 2024 PIPE, net of issuance costs		27,657,497
Proceeds from exercise of pre-funded warrants	3,050	28,038
Net cash provided by financing activities	20,944,670	27,875,809
Net (decrease) increase in cash	(7,174,611)	693,021
Cash at beginning of period	13,291,167	12,598,146
Cash at end of period	$ 6,116,556	$ 13,291,167
Noncash financing activities		
Reclassification of July 2024 PIPE warrants from liability to equity	$ —	$ 8,689,148
Decrease in share-based compensation liability on CAD denominated share options increasing additional paid-in-capital	$ (170,081)	$ 222,739
July 22, 2025 deferred discount for fair value modification of warrants	$ 930,841	$ —
July 22, 2025 deferred discount issuance cost recognized on completion of PIPE	$ (930,841)	$ —
July 28, 2025 deferred discount for fair value modification of warrants	$ 1,794,146	$ —
July 28, 2025 deferred discount issuance cost recognized on completion of PIPE	$ (1,794,146)	$ —
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 76,775

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

PROMIS NEUROSCIENCES INC.

Notes to Consolidated Financial Statements

(expressed in U.S. dollars, except share and per share amounts)

1. DESCRIPTION OF BUSINESS

Business Description

ProMIS Neurosciences Inc. (the "**Company**" or "**ProMIS**") is applying its patented technology platform to build a portfolio of antibody therapies, therapeutic vaccines, and other antibody-based therapies in neurodegenerative diseases and other protein-misfolding diseases, with a focus on Alzheimer's disease (AD), multiple system atrophy (MSA), and amyotrophic lateral sclerosis (ALS). The Company believes these diseases share a common biologic cause — misfolded versions of proteins, that otherwise perform a normal function, becoming toxic and killing neurons, resulting in disease. ProMIS' technology platform enables drug discovery through a combination of protein biology, physics and supercomputing. ProMIS believes this platform provides a potential advantage in selectively targeting the toxic misfolded proteins with therapeutics or detecting them with diagnostics.

The Company is developing a pipeline of antibodies aimed at selectively targeting misfolded toxic forms of proteins that drive neurodegenerative diseases without interfering with the essential functions of the same properly folded proteins. The Company's product candidates are PMN310, PMN267, and PMN442. The lead product candidate is PMN310, a monoclonal antibody designed to treat AD by selectively targeting toxic, misfolded oligomers of amyloid-beta. PMN267 is our second lead product candidate targeting ALS. It has been shown in preclinical studies to selectively recognize misfolded, cytoplasmic TDP 43 aggregates without interacting with normal TDP 43. Misfolded TDP 43 is believed to play an important role in the development of ALS. In light of research suggesting that misfolded toxic a-syn is a primary driver of disease in synucleinopathies such as MSA and Parkinson's disease, our third lead product candidate, PMN442, has shown robust binding to pathogenic a-syn oligomers and seeding fibrils in preclinical studies, with negligible binding to a-syn monomers and physiologic tetramers which are required for normal neuronal function.

The Company was incorporated on January 23, 2004 under the Canada Business Corporations Act ("**CBCA**"). On July 13, 2023, the Company continued its existence from a corporation incorporated under the CBCA into the Province of Ontario under the Business Corporations Act (Ontario) ("**OBCA**") ("**Continuance**"). The Continuance was approved by the Company's shareholders at the Company's 2023 Annual Meeting of Shareholders held on June 29, 2023. The Company is located at 1920 Yonge Street, Toronto, Ontario. The Company's Common Shares are traded on the Nasdaq Capital Market ("**Nasdaq**") under the symbol PMN. The Company has a wholly-owned U.S. subsidiary, ProMIS Neurosciences (U.S.) Inc. ("**ProMIS USA**"), which was incorporated in January 2016 in the State of Delaware. As of December 31, 2025, ProMIS USA has had no material activity and has no material financial impact on the Company's consolidated financial statements.

Liquidity and Capital Resources

The accompanying consolidated financial statements were prepared on a going concern basis, which assumes that the Company will continue its operations for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of business. To date, the Company has not generated revenues from its activities. The Company had an operating loss of $40.2 million for the year ended December 31, 2025, an accumulated deficit of $130.4 million as of December 31, 2025, and negative cash flows from operations of $28.1 million for the year ended December 31, 2025. In January 2026, the Company received gross proceeds of $75.5 million from the sale of Common Shares, Common Share warrants, and pre-funded warrants to purchase Common Shares to external investors and certain of the Company's directors and management in a private placement. Fees and other expenses are currently not estimable by the Company, as they are still being determined. Refer to additional discussion in Note 14.

Based on the Company's current operating plan, the Company expects that its existing cash, including the proceeds from January 2026, will be sufficient to fund the Company's operating expenses and capital expenditure requirements through 2027. The Company based this estimate on assumptions that may prove to be wrong, and the Company could exhaust its available capital resources sooner than it expects, including based on its decision to initiate other clinical trials or programs.

Future capital requirements will depend upon many factors, including the timing and extent of spending on research and development and market acceptance of the Company's products, if approved for commercial sale. The Company will require additional funding to conduct future clinical activities. The Company expects to seek additional funding through public and private financings, debt financings, collaboration agreements, strategic alliances and licensing agreements. Although the Company has been successful in raising capital in the past, there is no assurance of success in obtaining such additional financing on terms acceptable to us, if at all, and there is no assurance that the Company will be able to enter into collaborations or other arrangements. If the Company is unable to obtain funding or other arrangements, it could force delays, reduce or eliminate research and development programs, and/or reduce product portfolio expansion or commercialization efforts, which could adversely affect future business prospects, and the ability to continue operations.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("**GAAP**"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("**ASC**") and as amended by Accounting Standards Updates ("**ASU**") of the Financial Accounting Standards Board ("**FASB**").

On November 17, 2025, the board of directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 25:1, effective November 28, 2025 (the "**Reverse Share Split**"). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make certain estimates, judgements and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of financial instruments. Actual results could differ from those estimates, and such differences could be material to the consolidated financial statements.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker ("**CODM**"), or decision-making group, in making decisions on how to allocate resources and assess performance. The Company has one operating segment and its Chief Executive Officer serves as the CODM. Substantially all of the Company's assets are located in Canada. Refer to additional Segment Information in Note 10.

Foreign and Functional Currency

The Company determines its functional currency as the currency of the primary economic environment in which the Company operates. To determine the primary economic environment, the Company considers salient economic factors, including cash flow indicators, expense indicators and financing indicators. Functional currency is a matter of fact, not a policy election and the Company will only reevaluate its functional currency if there is a significant change in facts and circumstances.

Prior to July 1, 2023, the Company's functional currency was the Canadian dollar ("**C$**"). Translation gains and losses from the application of the United States dollar ("**US$**") as the reporting currency during the period that the Canadian dollar was the functional currency were included as part of cumulative foreign currency translation adjustment, which is reported as a component of stockholders' (deficit) equity as accumulated other comprehensive loss.

Following the Company's voluntary delisting from the Toronto Stock Exchange in July 2023, the Company determined there was a significant change in its facts and circumstances, and completed a reassessment of its functional currency. The Company determined that, as of July 1, 2023, the Company's functional currency had changed from the C$ to the US$. The Company reassessment included analysis of various factors, including: the Company's cash flows and expenses denominated primarily in US$, the primary market for the Company's Common Shares trading in US$ and a majority ownership by U.S. shareholders from financings denominated in US$. The change in functional currency was accounted for prospectively from July 1, 2023 and consolidated financial statements prior to and including the period ended June 30, 2023 were not restated for the change in functional currency.

For periods commencing July 1, 2023, monetary assets and liabilities denominated in foreign currencies are translated into US$ using exchange rates in effect at the end of the reporting period. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets acquired, and non-monetary liabilities incurred after July 1, 2023 are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the consolidated statement of operations within operating expenses.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2025 and 2024, the Company did not have any material cash equivalents.

Short-term Investments

Short-term investments consist of guaranteed certificates of deposit with a maturity greater than 90 days and up to one year at the time of purchase. Accordingly, all short-term investments are classified as current assets in the accompanying consolidated balance sheets. The short-term investment is being held as collateral for the Company's credit cards.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash and short-term investments. Cash is deposited in checking and money market accounts at accredited financial institutions, which at times, may exceed federally insured limits. The short-term investment is deposited in a guaranteed certificate of deposit with an accredited financial institution that guarantees 100% of the original amount invested. As of December 31, 2025, the Company has not experienced any losses on its cash or short-term investments as a result of credit risk.

Fair Value Measurements

FASB ASC 820, *Fair Value Measurements and Disclosures,* (**"ASC 820"**) defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, as established by ASC 820, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Observable inputs, such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

- Level 2 – Inputs (other than Level 1 quoted prices) are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities.

- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation 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. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's warrant liabilities were classified as Level 3 financial instruments for the year ended December 31, 2024. The Company's share-based compensation liability was classified as a Level 3 financial instrument for the years ended December 31, 2025 and 2024.

The carrying amounts of prepaid and other current assets, short-term investments, accounts payable, and accrued expenses are generally considered to be representative of their fair value based on the short-term nature of these financial instruments.

Impairment of Long-lived Assets

The Company historically evaluates its long-lived assets, which consist of property and equipment and definite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. The Company did not have any material long-lived assets as of December 31, 2025 and 2024.

Property and Equipment

Property and equipment, net are historically stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset. Laboratory and equipment are depreciated over two to five years. Computer equipment is depreciated over two to three years. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accompanying consolidated balance sheets and any resulting gain or loss is included in loss from operations in the accompanying consolidated statements of operations. Expenditures for repairs and maintenance are expensed as incurred. The Company did not have any material property and equipment as of December 31, 2025 and 2024.

Intangible Assets

Definite-lived intangible assets are historically stated at cost less accumulated amortization and any accumulated impairment losses. An intangible asset's carrying amount is assessed for impairment whenever there is an indication that the asset may be impaired. The Company's definite-lived intangible assets consist of acquired rights and patents. Intangible assets are amortized on a straight-line basis over the lesser of the life of the intangible asset or its estimated useful life, which is 15 years. The Company did not have any material intangible assets as of December 31, 2025.

Collaboration Arrangements

The Company may enter into collaboration arrangements with pharmaceutical and biotechnology partners. The Company analyzes its collaboration arrangements to assess whether they are within the scope of FASB ASC 808, *Collaborative Arrangements,* (**"ASC 808"**), to determine whether such arrangements involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in responsibilities of all parties in the arrangement. ASC 808 does not provide guidance on the recognition of consideration exchanged or accounting for the obligations that may arise between parties. The Company concluded that ASC Topic 730, *Research and Development,* should be applied by analogy to payments between parties during the development activities of its collaboration arrangements.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs including salary, bonus, employee-benefits and share-based compensation, costs incurred in development and protection of intellectual property, professional service fees, and other general overhead and facility costs, including rent, depreciation and amortization, which relate to the Company's general and administrative functions.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development and research of the Company's platform technology, as well as discovery program expenses. The Company expenses research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and share-based compensation expense, for employees engaged in research and development functions;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("**CROs**"), and consultants;
- the cost of acquiring, developing, and manufacturing clinical study materials; and

- Costs associated with preclinical and clinical activities and regulatory operations.

Prepaid and Accrued Research and Development Expenses

Substantial portions of the Company's pre-clinical development, manufacturing and clinical trials are performed by third-party laboratories, medical centers, CROs and other vendors. These vendors generally bill monthly for services performed, or bill based upon milestone achievement. For preclinical and clinical studies, the Company accrues expenses based upon estimated work completed and the remaining contract milestones. At times, the Company is obligated to make upfront payments upon execution of research and development agreements. Upfront payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses until such goods are delivered or the related services are performed. The Company estimates the period over which such services will be performed based on the terms of the agreements as well as the level of effort to be expended in each period. The actual timing of performance or the level of effort may vary from the estimate, and if that does occur, the Company will adjust the amounts recorded accordingly.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying consolidated statements of operations.

Warrants

The Company issues warrants, including pre-funded warrants, on its common shares in connection with financings as well as for compensation of intermediaries and advisors. The Company accounts for warrants as either equity instruments or as liabilities depending on the specific terms of the warrant agreements in accordance with FASB ASC Topic 815, *Derivatives and Hedging* and Topic 480, *Distinguishing Liabilities from Equity*. When classified as equity, warrants are recorded within additional paid-in-capital at the time of issuance and are not subsequently remeasured. Warrants identified as meeting the definition of a liability are recognized as a liability and treated in accordance with the derivative liability accounting policy described above. The Company periodically reassesses the appropriateness of the classification of its financial instruments.

Share-based Compensation

Share-based compensation expense related to share awards granted to employees, directors and non-employees, excluding awards with market conditions in which the award does not vest unless the market condition is met, is recognized based on the grant-date estimated fair values of the awards using the Black- Scholes option pricing model ("**Black-Scholes**"). The value is recognized as expense ratably over the requisite service period, which is generally the vesting term of the award. The Company adjusts the expense for actual forfeitures as they occur. Share-based compensation expense is classified in the accompanying consolidated statements of operations based on the function to which the related services are provided.

Black Scholes requires a number of assumptions, of which the most significant are expected volatility, expected option term (the time from the grant date until the options are exercised or expire) and risk-free rate. Expected volatility is determined using the historical volatility for the Company. The risk-free interest rate is based on the yield of U.S. government treasury bonds with a remaining term equal to the expected life of the option for C$ options and based on the yield of U.S. government treasury bonds for US$ options. Expected dividend yield is zero because the Company has never paid cash dividends on common shares and the Company does not expect to pay cash dividends in the foreseeable future.

For awards with market conditions in which the award does not vest unless the market condition is met, the Company will incorporate the market condition into the award's grant date fair value calculation and derive the expected service period using a Monte Carlo simulation. The estimated expense is recognized on a straight-line

basis over the derived service period. If the market condition is satisfied during the derived service period, the remaining unrecognized expense is recognized during the period the market condition is satisfied.

Awards of options that provide for an exercise price that is not denominated in: (a) the currency of a market in which a substantial portion of the Company's equity securities trades in, (b) the currency in which the employee's pay is denominated, or (c) the Company's functional currency, are required to be classified as liabilities. The change in the Company's functional currency, effective July 1, 2023, resulted in the reclassification of outstanding stock options that were previously denominated in C$ from equity-classified to liability-classified options (see Note 8), which are accounted for as a share option modification in accordance with FASB's ASC 718 – *Compensation – Stock Compensation* ("**ASC 718**"). Under ASC 718, when an award is reclassified from equity to liability, if at the reclassification date the original vesting conditions are expected to be satisfied, then the minimum amount of compensation cost to be recognized is based on the grant date fair value of the original award. Fair value changes below this minimum amount are recorded in additional paid-in capital. For each reporting period after the modification date, the stock option liability is adjusted so that it equals the portion of the requisite service provided multiplied by the modified award's fair value at the end of the reporting period. Increases in the fair value of the liability in excess of the minimum grant date compensation cost described above are recognized as share-based compensation in operating expenses in the consolidated statement of operations.

Share Issuance Costs

Common share issuance costs are incremental costs directly associated with an offering of securities. These costs typically include fees paid to bankers or underwriters, attorneys, accountants, as well as printers and other third parties. Prior to the effective date of an offering of equity securities, specific incremental costs directly attributable to a proposed or actual offering of securities may be deferred and charged against the gross proceeds of the offering. The Company capitalizes these deferred financing costs as prepaid expenses and other current assets in the accompanying consolidated balance sheets until the completion of the offering, unless the offering is abandoned, at which time the deferred financing costs will be recognized in the consolidated statements of operations. The Company had approximately $32,000 and $0 in deferred financing costs as of December 31, 2025 and December 31, 2024, respectively, which was recorded in prepaid expenses and other current assets on the consolidated balance sheets.

Income Taxes

The Company is a taxable entity under the Income Tax Act (Canada). Deferred income tax assets and liabilities are determined based on differences between the financial statement carrying amounts and the respective income tax bases of assets and liabilities, measured using substantively enacted income tax rates and laws that are expected to be in effect when the differences are expected to reverse. Deferred tax assets are recognized to the extent it is more likely than not that taxable income will be available against which the deferred tax asset can be utilized. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company follows the provisions of ASC 740-10, *Uncertainty in Income Taxes* ("**ASC 740-10**"). The Company has not recognized a liability as a result of the implementation of ASC 740-10. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there is no unrecognized benefit since the date of adoption. The Company has not recognized interest expense or penalties as a result of the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses.

Basic and Diluted Net (Loss) Income Per Share

Basic net (loss) income per common share is based upon the weighted-average number of common shares outstanding during the period. Diluted net (loss) income per common share utilizing the treasury-stock method is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive. Potentially

dilutive shares result from the assumed potential exercise or conversion of securities, such as convertible debt, share options and warrants, which would result in the issuance of incremental shares of common shares. The proceeds of such exercises or conversions are assumed to have been used to repurchase outstanding stock using the treasury stock method.

Both basic and diluted net (loss) income per share calculations include financial instruments that allow for the purchase of common shares issuable for little to no consideration, including pre-funded warrants.

Emerging Growth Company Status

The Company is an Emerging Growth Company, as defined in Section 2(a) of the Securities Act of 1933, as modified by the Jumpstart Our Business Startups Act of 2012 ("**JOBS Act**"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

In 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires public entities to disclose in their rate reconciliation table additional categories of information about federal, state and foreign income taxes and to provide more details about the reconciling items in some categories if items meet a quantitative threshold. ASU 2023-09 became effective for the annual period starting on January 1, 2025. The Company's income tax disclosures are disclosed in Note 9.

Recently Issued Accounting Pronouncements

In 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220- 40): Disaggregation of Income Statement Expenses ("ASU 2024-03"), which requires public entities, among other items, to disclose in a tabular format, on an annual and interim basis, purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. ASU 2024-03 becomes effective for the annual period starting on January 1, 2027 and interim periods starting on January 1, 2028. The Company is in the process of analyzing the impact that the adoption of ASU 2024-03 will have on its disclosures.

3. FAIR VALUE MEASUREMENTS

The following are the major categories of assets measured at fair value on a recurring basis as of December 31, 2025 and 2024:

	As of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Short-term investments	$ 33,753	$ —	$ —	$ 33,753
Total assets measured at fair value	$ 33,753	$ —	$ —	$ 33,753
Liabilities:				
Share-based compensation liability	$ —	$ —	$ 29,182	$ 29,182
Total liabilities measured at fair value	$ —	$ —	$ 29,182	$ 29,182

	As of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Short-term investments	$ 33,051	$ —	$ —	$ 33,051
Total assets measured at fair value	$ 33,051	$ —	$ —	$ 33,051
Liabilities:				
Share-based compensation liability	$ —	$ —	$ 199,263	$ 199,263
Warrant liability	—	—	5,592	5,592
Total liabilities measured at fair value	$ —	$ —	$ 204,855	$ 204,855

No transfers between levels have occurred in either reporting period presented. Refer to Note 6 for disclosures related to the warrant liability and Note 8 for disclosures related to share-based compensation liability.

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2025	2024
Upfront research payments	$ 2,625,049	$ 5,087,692
Accrued interest and other receivables	36,522	78,034
Insurance	238,000	335,976
License fees	62,059	38,255
Deferred financing costs	32,332	—
Other	38,150	47,281
Total prepaid expenses and other current assets	$ 3,032,112	$ 5,587,238

5. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	December 31,	
	2025	2024
Legal	$ 88,411	$ 44,610
Accounting	159,900	95,182
Research and development	7,460,614	223,559
Severance	79,748	38,328
Other	79,743	79,283
Accrued liabilities	$ 7,868,416	$ 480,962

6. EQUITY

The Company has authorized an unlimited number of both Common and Preferred shares. As of December 31, 2025 and 2024, the Company had 2,152,397 and 1,307,520 issued and outstanding Common Shares, respectively. All share classes have no par value.

Common Shares reserved for future issuance consists of the following:

	December 31, 2025
Warrants	2,639,005
Options issued and outstanding under stock option plan	180,827
Deferred Share Units granted	42
Common Shares available for grant under stock option plan	80,686
Total Common Shares reserved for future issuance	2,900,561

Common Shares

The preferences, privileges, and rights of the Common Shares are as follows:

Voting

Subject to any special voting rights or restrictions, holders of common shares entitled to vote shall have one vote per share.

Dividends

The Company's board of directors may from time to time declare and authorize payment of dividends, if any, as they may deem advisable and need not give notice of such declaration to any shareholder. Subject to the rights of common shareholders, if any, holding shares with specific rights as to dividends, all dividends on common shares shall be declared and paid according to the number of such shares held and paid in Canadian dollars.

Liquidation Rights

In the event of the liquidation, dissolution or winding-up of the Company or any other distribution of the Company's assets for the purpose of winding up the Company's affairs, after the payment of dividends declared but unpaid, the holders of Common Shares shall be entitled *pari passu* to receive any remaining property of the Company.

Equity Transactions

July 2024 Private Placement

On July 26, 2024, the Company entered into a Unit Purchase Agreement (the "**Unit Purchase Agreement**") to raise $30,332,984 in aggregate gross proceeds for the Company (the "**July 2024 PIPE**") before deducting $2,675,487 in placement agent fees and other expenses. All gross proceeds were received by the Company as of December 31, 2024.

Pursuant to the terms of the Unit Purchase Agreement, the Company agreed to sell to PIPE Investors in the Offering, an aggregate of (x) 390,307 common share units (the "**Common Share Units**"), each consisting of (i) one Common Share, (ii) one Tranche A Common Share purchase warrant to purchase one Common Share, (iii) one Tranche B Common Share purchase warrant to purchase one Common Share and (iv) one Tranche C Common Share purchase warrant to purchase one Common Share (each, a "**Warrant**", collectively, the "**Warrants**") and, for certain investors, (y) 174,841 pre-funded units (the "**Pre-Funded Units**" and together with the Common Share Units, the "**Units**"), each consisting of (i) one Pre-Funded Warrant to purchase one Common Share (each, a "**Pre-Funded Warrant**", collectively, the "**Pre-Funded Warrants**", and the Common Shares issuable upon exercise of the Warrants and the Pre-Funded Warrants, the "**2024 Warrant Shares**"), (ii) one Tranche A Common Share purchase warrant to purchase one Common Share, (iii) one Tranche B Common Share purchase warrant to purchase one Common Share and (iv) one Tranche C Common Share purchase warrant to purchase one Common Share.

The purchase price for each Common Share Unit was $53.75 per Common Share Unit, and the purchase price for each Pre-Funded Unit was $53.50 per Pre-Funded Unit. The Pre-Funded Warrants have an exercise price of $0.25 per 2024 Warrant Share, are immediately exercisable and will expire when exercised in full. The Tranche A Common Share purchase warrants have an exercise price of $50.50, for aggregate gross proceeds of up to $28.5 million, are exercisable immediately upon Shareholder Approval (as defined below) and will expire upon the earlier of (i) 18 months or (ii) within 60 days of the Tranche A Milestone Event (as defined below). The Tranche B Common Share purchase warrants have an exercise price of $50.50, for aggregate gross proceeds of up to $28.5 million, are exercisable immediately upon Shareholder Approval (as defined below) and will expire upon the earlier of (i) 30 months or (ii) within 60 days of the Tranche B Milestone Event (as defined below). The Tranche C Common Share purchase warrants have an exercise price of $62.50, for aggregate gross proceeds of up to $35.3 million, are immediately exercisable and will expire on July 31, 2029. For purposes of the foregoing, "**Tranche A Milestone Event**" means the public announcement via press release or the filing of a Current Report on Form 8-K of 6-month data from the cohorts treated with multiple ascending doses of PMN310, and "**Tranche B Milestone Event**" means the public announcement via press release or the filing of a Current Report on Form 8-K of 12-month data from the cohorts treated with multiple ascending doses of PMN310. Pursuant to Nasdaq Listing Rule 5635(d), the exercise of the Tranche A and Tranche B Common Share purchase warrants is subject to shareholder approval ("**Shareholder Approval**"). The Company agreed to convene a shareholders' meeting, or otherwise obtain written Shareholder Approval, on or before 90 days following the Closing Date, to obtain such approval.

The Tranche A and Tranche B Warrants ("**AB Warrants**") were classified as liabilities ("**AB Warrant Liability**") and recorded at fair value utilizing level 3 inputs at issuance due to the requirement for Shareholder Approval. Under the applicable accounting guidance, the requirement for Shareholder Approval precludes a financial instrument from equity classification, as it cannot be considered indexed to the Company's own stock. The preclusion is because of the potential of the settlement amount differing than a fixed for fixed option on the Company's shares. The fair value of the AB Warrant Liability at issuance was determined to be $31,182,033, calculated using a Black Scholes calculation on July 26, 2024 with the following weighted average assumptions: share price of $50.50, the most currently available Nasdaq Official Closing Price for the Company's Common Shares when the Company entered into the purchase agreements, exercise price of $50.50, volatility of 102.5%, risk-free rate of 4.34%, and a term of 2.1 years.

The Company incurred offering costs totaling $2,675,487 that consisted of placement agent fees and direct incremental legal, advisory, accounting and filing fees relating to the July 2024 PIPE, resulting in net cash proceeds of $27,657,497. The value of the AB Warrants exceeded the net proceeds received. As a result, the entire proceeds and offering costs were allocated to the AB Warrant liability, and also resulted in a loss on issuance of common shares, warrants, and pre-funded warrants of $3,524,535, which was recorded in other income (expense) in the consolidated statements of operations.

On October 23, 2024, Shareholder Approval for the AB Warrants was obtained during the Company's Special Meeting of Shareholders. Following Shareholder Approval, the Company determined that the AB Warrants met the criteria for equity classification. The Company re-measured the fair value of the AB Warrant Liability at October 23, 2024 to $8,689,149, calculated using a Black Scholes calculation with the following weighted average assumptions: volatility of 100.9%, share price of $23.75, exercise price of $50.50, risk-free rate of 4.10%, and a term of 1.9 years. The change in fair value of the AB Warrant Liability of $22,492,884 was recorded in other income (expense) in the consolidated statements of operations and the remaining fair value of $8,689,149 was reclassified from liability to additional paid-in-capital in the consolidated balance sheets. As of December 31, 2025, 942,510 warrants issued with the July 2024 PIPE are outstanding (314,170 each from Tranche A, Tranche B, and Tranche C).

A summary of warrant liability activity, which is based on level 3 inputs, for the years ended December 31, 2025 and 2024 is as follows:

	December 31, 2025
Fair value at December 31, 2024	$ 5,592
Change in fair value of C$ warrant liability	(5,592)
Fair value at December 31, 2025	$ —

	December 31, 2024
Fair value at December 31, 2023	$ 94,185
July 2024 PIPE AB Warrant Liability at issuance	31,182,033
Change in fair value of 2024 PIPE AB Warrant Liability	(22,492,884)
Reclassification of 2024 PIPE AB Warrant Liability to equity	(8,689,149)
Change in fair value of C$ warrant liability	(88,593)
Fair value at December 31, 2024	$ 5,592

July 2025 Registered Direct Offering

On July 22, 2025, the Company entered into a securities purchase agreement relating to the issuance and sale of a pre-funded warrant to purchase 39,389 Common Shares (the "**RD Pre-funded Warrant**") to such investor (the "**RD Offering**"). The RD Pre-funded Warrant was sold at an offering price of $20.31 per share, which represents, if it were applicable, the per share offering price for the Common Shares of the Company, less a $0.0025 per share exercise price for such Pre-funded Warrant. The gross proceeds from the RD Offering were $800,000 before deducting offering expenses of $102,342.

July 22, 2025 Exercise of Discounted Warrants and PIPE

On July 22, 2025, the Company accepted a discounted warrant exercise offer from a healthcare-focused institutional investor for certain July 2024 PIPE warrants ("**July 22, 2025 Discounted Exercise**"). Related to the July 22, 2025 Discounted Exercise, the Company also entered into a securities purchase agreement (the "**July 22, 2025 PIPE**") with the same existing healthcare-focused institutional investor. The Company raised $9,199,765 in aggregate gross proceeds from the July 22, 2025 Discounted Exercise and July 22, 2025 PIPE before deducting $808,738 in transaction costs paid by the Company.

In the July 22, 2025 Discounted Exercise, the Company issued 336,449 Common Shares in exchange for the exercise of 336,449 of the July 2024 PIPE warrants (112,150 each from Tranche A, Tranche B, and Tranche C) for $20.31 per warrant. The Company determined that discounting the exercise price represented a modification of the July 2024 PIPE warrants. In accordance with *ASC815 – Derivatives and Hedging* ("**ASC 815**"), the Company accounted for the incremental fair value of the modification as the difference between the pre-modification fair value and the post-modification fair value of the July 2024 PIPE warrants, as calculated using Black-Scholes. The modification date incremental fair value of $930,841 was initially recorded as a deferred financing cost, as the discount was directly attributable to a proposed offering, and was subsequently recognized as an equity issuance cost upon the closing of the July 22, 2025 Discounted Exercise and July 22, 2025 PIPE. The range of valuation inputs used in the pre-modification fair value Black Scholes calculation of the July 2024 PIPE warrants included a share price of $14.70, exercise prices of $50.50-$62.50, time to maturity of 0.53-4.02 years, risk free rate of 3.9%-4.3%, and annualized volatility of 106.5%. The post-modification fair value Black Scholes calculation used the same fair value inputs as the pre-modification fair value calculation apart from the modified exercise price of $20.31.

Pursuant to the terms of the July 22, 2025 PIPE, the Company agreed to sell a warrant to purchase 504,673 Common Shares (the "**July 22, 2025 Warrant**"). The July 22, 2025 Warrant was sold to the investor at an offering price of $4.69 per share and has an exercise price of $31.25 per share.

The July 22, 2025 Warrant is immediately exercisable and will expire five years after the date of issuance. The holder of the July 22, 2025 Warrant may not exercise it if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of Common Shares outstanding immediately after giving effect to such exercise.

The Company determined the July 22, 2025 Warrant met the permanent equity criteria classification. The July 22, 2025 Warrant is classified as a component of permanent equity because it is a freestanding financial instrument, is immediately exercisable, does not embody an obligation for the Company to repurchase its shares, and permits the holders to receive a fixed number of common shares upon exercise. In addition, the July 22, 2025 Warrant does not provide any guarantee of value or return. The Company used a Black-Scholes calculation to determine the fair value of the July 22, 2025 Warrant at issuance and allocated a share of the net proceeds based on the relative fair value of the July 22, 2025 Warrant. Net proceeds allocated to the July 22, 2025 Warrant were $4,284,557, with the remaining net proceeds of $4,106,470 allocated to the Common Shares issued in the July 22, 2025 Discounted Exercise. The aggregate net proceeds of $8,391,027 are recorded in additional paid-in-capital. The valuation inputs used in the Black Scholes calculation of the July 22, 2025 Warrant at issuance included a share price of $14.70, exercise price of $31.25, time to maturity of 5 years, risk free rate of 3.9%, and annualized volatility of 106.5%.

July 28, 2025 Exercise of Discounted Warrants and PIPE

On July 28, 2025, the Company accepted discounted warrant exercise offers for certain July 2024 PIPE warrants ("**July 28, 2025 Discounted Exercise**"). Related to the July 28, 2025 Discounted Exercise, the Company also entered into a securities purchase agreement (the "**July 28, 2025 PIPE**") with the same existing investors. The Company raised $11,623,047 in aggregate gross proceeds from the July 28, 2025 Discounted Exercise and July 28, 2025 PIPE before deducting $478,580 in transaction costs paid by the Company.

In the July 28, 2025 Discounted Exercise, the Company issued 416,436 Common Shares in exchange for the exercise of 416,436 of the July 2024 PIPE warrants (138,812 each from Tranche A, Tranche B, and Tranche C) for $20.88 per warrant. The Company determined that discounting the exercise price represented a modification of the July 2024 PIPE warrants. In accordance with ASC 815, the Company accounted for the incremental fair value of the modification as the difference between the pre-modification fair value and the post-modification fair value of the July 2024 PIPE warrants, as calculated using Black-Scholes. The modification date incremental fair value of $1,794,146 was initially recorded as a deferred financing cost, as the discount was directly attributable to a proposed offering, and was subsequently recognized as an equity issuance cost upon the closing of the July 28, 2025 Discounted Exercise and July 28, 2025 PIPE. The range of valuation inputs used in the pre-modification fair value Black Scholes calculation of the July 2024 PIPE warrants included a share price of $20.88, exercise prices of $50.50-$62.50, time to maturity of 0.52-4.01 years, risk free rate of 3.9%-4.3%, and annualized volatility of 107.4%. The post-modification fair value Black Scholes calculation used the same fair value inputs as the pre-modification fair value calculation apart from the modified exercise price of $20.88.

Pursuant to the terms of the July 28, 2025 PIPE, the Company agreed to sell warrants to purchase 624,654 Common Shares (the "**July 28, 2025 Warrants**"). The July 28, 2025 Warrants were sold to the investor at an offering price of $0.1875 per share and has an exercise price of $31.25 per share.

The July 28, 2025 Warrant are immediately exercisable and will expire five years after the date of issuance. Certain holders of the July 28, 2025 Warrants may not exercise it if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of Common Shares outstanding immediately after giving effect to such exercise.

The Company determined the July 28, 2025 Warrants met the permanent equity criteria classification. The July 28, 2025 Warrants are classified as a component of permanent equity because they are a freestanding financial instrument, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of common shares upon exercise. In addition, the July 28, 2025 Warrants do not provide any guarantee of value or return. To determine the fair value of the July 28, 2025 Warrants at issuance, the Company used a Black-Scholes model and allocated a share of the net proceeds based on the relative fair value of the July 28, 2025 Warrants. Net proceeds allocated to the July 28, 2025 Warrants were $5,885,032, with the remaining net proceeds of $5,259,435 allocated to the Common Shares issued in the July 28, 2025 Discounted Exercise. The aggregate net proceeds of $11,144,467 are recorded in additional paid-in-capital. The valuation inputs used in the Black Scholes calculation of the July 28, 2025 Warrant at issuance included a share price of $20.88, exercise price of $31.25, time to maturity of 5 years, risk free rate of 4.0%, and annualized volatility of 107.4

November 2025 Reverse Share Split

On November 28, 2025, the Company filed articles of amendment to effect a one-for-twenty-five reverse share split of its Common Shares (the "**Reverse Share Split**"). As a result of the Reverse Share Split, every 25 Common Shares issued or outstanding were automatically reclassified into one validly issued, fully paid and non-assessable new Common Share, subject to the treatment of fractional shares as described below, without any action on the part of the holders. Proportional adjustments were made to the number of Common Shares awarded and available for issuance under the Company's equity incentive plans, as well as the exercise price and the number of shares issuable upon the exercise or conversion of the Company's outstanding stock options and other equity securities under the Company's equity incentive plans. All outstanding warrants were also adjusted in accordance with their terms, which resulted, among other changes to the warrant terms, in proportionate adjustments being made to the number of shares issuable upon exercise of such warrants and to the exercise prices of such warrants. The Common Shares outstanding following the Reverse Share Split remain fully paid and non-assessable. The Reverse Share Split did not affect the number of authorized Common Shares or the par value of the Common Shares. All share and per-share amounts have been retroactively adjusted to reflect the Reverse Share Split.

At-the-Market Offerings (ATM)

In September 2023, the Company filed a shelf registration statement with the SEC. In conjunction with the shelf registration, the Company entered into an ATM agreement in January 2024 (the "**2024 ATM Agreement**") to offer up to $25.0 million of the Company's Common Shares. During the year ended December 31, 2024, the Company sold 3,034 Common Shares for net proceeds of $190,274 after deducting sales commissions. The 2024 ATM Agreement was terminated in July 2025.

In August 2025, the Company filed a shelf registration statement with the SEC. In conjunction with the shelf registration, the Company entered into an ATM Agreement with H.C. Wainwright & Co., LLC (the "**2025 ATM Agreement**") on August 26, 2025 to offer up to $18.0 million of its Common Shares. During the year ended December 31, 2025, the Company sold 40,795 Common Shares for net proceeds of $708,468 after deducting sales commissions pursuant to the 2025 ATM Agreement.

7. WARRANTS

As of December 31, 2025, outstanding Common Share warrants and exercise prices related to unit offerings are as follows:

Exercise Price $	Number of Warrants	Expiry date
US$50.50	314,170	January 2026
US$315.00	20,948	August 2026
US$240.00	5,868	August 2026
US$50.50	314,170	January 2027
US$187.50	13,831	April 2028
US$152.50	2,767	April 2028
US$43.75	449,084	February 2029
US$62.50	314,170	July 2029
US$31.25	1,129,324	July 2030
US$0.25	74,673	None
	2,639,005	

During the year ended December 31, 2025, 51,197 pre-funded warrants, including 39,389 issued in the July 2025 RD Offering, were exercised for gross proceeds of $3,050. Refer to Note 6 for discussion on the discounted exercise of 336,449 July 2024 PIPE warrants on July 22, 2025, discounted exercise of 416,436 July 2024 PIPE warrants on July 28, 2025, issuance of 504,673 new warrants in the July 22, 2025 PIPE, and issuance of 624,654 new warrants in the July 28, 2025 PIPE. During the year ended December 31, 2025, 11,184 warrants expired without being exercised.

During the year ended December 31, 2024, 16,319 warrants expired without being exercised, and 112,150 pre-funded warrants were exercised for an equivalent number of common shares for net proceeds of $28,038.

8. SHARE-BASED COMPENSATION

2025 Stock Option Plan

At its June 2025 Annual Meeting of Shareholders, the Company's 2025 Stock Option and Incentive Plan (**"2025 Option Plan")** was approved by the shareholders. The 2025 Option Plan replaces the 2015 Stock Option Plan (**"2015 Option Plan"**), originally referred to as the 2007 Option Plan. No new awards can be issued under the 2015 Option Plan. The Company reserved 117,868 Common Shares for issuance under the 2025 Option Plan at the time of adoption. As of December 31, 2025 and 2024, the Company had 80,686 and 118,535 options available for grant under the 2025 Option Plan and 2015 Option Plan, respectively. The Common Shares underlying any awards under the 2025 Option Plan and 2015 Option Plan that are forfeited, canceled, or otherwise terminated (other than by exercise) are added back to the shares available for issuance under the 2025 Option Plan. Share options are granted in either USD or CAD. Upon the change in the Company's functional currency, effective July 1, 2023, CAD share options previously classified as equity were reclassified as liabilities. All grants following the Company's change in functional currency are in USD.

Canadian Dollar Share Options

The following table summarizes the activity of the C$ share options under the 2015 Option Plan for the years ended December 31, 2025 and 2024. All amounts are denominated in Canadian dollars, except year and share amounts:

	Number of Share Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2024	35,930	C$ 189.50	6.5	$ —
Expired	(3,191)	229.00		
Outstanding as of December 31, 2024	32,740	184.00	6.6	—
Forfeited	(2,346)	209.00	—	—
Expired	(14,704)	54.58	—	—
Outstanding as of December 31, 2025	15,690	C$ 170.00	6.0	—
Vested and exercisable as of December 31, 2025	15,413	C$ 170.50	6.0	$ —

The aggregate intrinsic value of options outstanding, exercisable, and vested and exercisable is calculated as the difference between the exercise price of the underlying options, and the fair value of the Company's Common Shares. There were no C$ share options granted during the years ended December 31, 2025 or 2024.

Upon the change in the Company's functional currency effective July 1, 2023 C$ share options previously classified as equity were reclassified as liabilities. The C$ options were re-measured as of December 31, 2024 and had a fair value of $199,263.

A summary of share-based compensation liability activity, measured using level 3 fair value inputs, for the year ended December 31, 2025 is as follows:

	December 31, 2025
Fair value at December 31, 2024	$ 199,263
Increase in additional paid-in-capital due to decrease in fair value of share-based compensation liability	(170,081)
Fair value at December 31, 2025	$ 29,182

A summary of share-based compensation liability activity for the year ended December 31, 2024 is as follows:

	December 31, 2024
Fair value at December 31, 2023	$ 422,002
Increase in additional paid-in-capital due to decrease in fair value of share-based compensation liability	(222,739)
Fair value at December 31, 2024	$ 199,263

The following table summarizes the weighted average of significant assumptions used to calculate the fair value of C$ share options using the Black Scholes option pricing model:

	Period Ended	
	December 31, 2025	December 31, 2024
Weighted average fair value of C$ Options	C$ 0.08	C$ 0.26
Expected volatility	106.4 %	99.7 %
Risk-free interest rate	3.86 %	4.40 %
Expected dividend yield	— %	— %
Expected term (years)	6.0	6.6

Expected volatility is based on historical volatility of the Company's Common Shares over the expected life of the option, as the Company's options are not readily tradable.

U.S. Dollar Share Options

The Company began making share option grants denominated in US$ following the Company's change in functional currency in July 2023. The following table summarizes the US$ share options outstanding under the 2015 Option Plan for the years ended December 31, 2025 and 2024. All amounts are denominated in US$, except year and share amounts:

	Number of Share Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2024	2,760	$ 46.75		$ —
Granted	107,478	27.75		
Outstanding as of December 31, 2024	110,238	28.25		—
Granted	55,400	11.81		—
Forfeited	(501)	46.75		
Outstanding as of December 31, 2025	165,137	22.75	9.0	—
Vested and exercisable as of December 31, 2025	47,421	$ 28.50	8.6	$ —

The grant date fair value of 55,400 and 107,478 US$ share options granted during the years ended December 31, 2025 and 2024, respectively, was estimated using Black Scholes with the following assumptions:

	Year Ended	
	December 31, 2025	December 31, 2024
Weighted average fair value of US$ Options	$ 9.80	$ 22.00
Expected volatility	107.4 %	101.7 %
Risk-free interest rate	3.79 %	3.95 %
Expected dividend yield	— %	— %
Expected term (years)	6.0	5.7

In October 2024, the Company granted its Chief Executive Officer 19,614 options with an exercise price of $28.75, which will begin vesting if and when the Company's 10-day VWAP of its Common Shares trading on the Nasdaq Capital Market meets or exceeds $86.25. The Company determined the share price requirement to begin vesting represented a market condition and performed a Monte-Carlo simulation to determine the fair value of the award, discounted for the likelihood of achieving the market condition. The resulting fair value of the option award was $383,000, with $168,946 and $39,344 recognized during the years ended December 31, 2025

and 2024 in the accompanying consolidated statement of operations, with the remaining $174,710 expected to be recognized over approximately 1.4 years.

DSU Plan

The Company has a Deferred Share Unit plan ("**DSU Plan**") for senior officers. Under the DSU Plan, rights to the Company's Common Shares may be awarded on a deferred payment basis up to a maximum of 667 common share units. Each common share unit will fully vest upon cessation of employment with the Company and then can be redeemed for one common share of the Company by the unitholder. The Company has 42 units outstanding as of December 31, 2025.

Share-based Payment Expense

The following table summarizes total share-based compensation for both the C$ and US$ share options included in the Company's accompanying consolidated statements of operations:

	Year Ended December 31,	
	2025	2024
Research and development	$ 37,674	$ 49,405
General and administrative	819,954	776,403
Total share-based compensation	$ 857,628	$ 825,808

As of December 31, 2025, there was $1,265,556 of unrecognized share-based compensation related to US$ options outstanding, which is expected to be recognized over a weighted-average remaining service period of 2.7 years. There was no material liability yet to be recognized for C$ share-based compensation as of December 31, 2025.

9. INCOME TAXES

As of December 31, 2025 and 2024, the net deferred tax assets have not been recognized in the accompanying consolidated financial statements. A valuation allowance is recognized to reduce the deferred tax asset as it is more likely than not that a tax benefit will not be realized.

The following are the significant components of the Company's deferred taxes as of December 31:

	2025	2024
Non-capital losses carried forward	$ 34,810,450	$ 24,850,000
Research and development expenditures	3,022,831	3,175,000
Investment tax credits	1,944,821	2,043,000
Tax value of technology rights and property and equipment in excess of accounting basis	160,999	193,000
Share issue costs	1,066,620	1,275,000
Non-deductible reserves	—	10,000
Restricted interest and financing expenses	—	337,000
Total deferred income tax assets	41,005,721	31,883,000
Valuation allowance	(41,005,721)	(31,883,000)
Net deferred income tax assets	$ —	$ —

As of December 31, 2025, the Company has available research and development expenditure credits for income tax purposes of approximately $11,407,000, which may be carried forward without expiration to reduce future taxable income.

As of December 31, 2025, the Company has non-capital income tax loss carry-forwards of approximately $131,360,190 available to reduce future income for income tax purposes. The income tax loss carry-forwards have expiry dates between the years 2026 and 2046.

As of December 31, 2025, the Company has approximately $2,553,000 of non-refundable investment tax credits available to offset future income taxes. The non-refundable investment tax credits have expiry dates between 2025 and 2035.

A reconciliation of the combined federal and provincial statutory income tax rate applied to the net (loss) income for the year to the income tax recovery as of December 31 is as follows:

	Year Ended December 31, 2025	
	Amount ($)	Percent (%)
Canadian federal statutory income tax rate	(5,960,583)	15.0 %
Provincial taxes (Ontario)	—	11.5
Non-deductible expenses	127,981	(0.3)
Share issue costs recorded, net of equity	(372,011)	0.9
Change in valuation allowance	6,027,731	(26.8)
Return to provision adjustments	15,444	(0.1)
Other	161,438	(0.3)
Effective Tax Rate	—	—

The Company does not expect a significant change in the amount of unrecognized tax benefits over the next 12 months. However, any adjustments arising from certain ongoing examinations by tax authorities could alter the timing or amount of taxable income or deductions and these adjustments could differ from the amount accrued. The Company's federal and provincial income tax returns files for all years remain subject to examination by the taxation authorities.

10. Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment: life science. The life science segment consists of the development of clinical and preclinical product candidates. The Company's chief operating decision maker ("**CODM**") is the chief executive officer.

The accounting policies of the life science segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the life science segment based on net (loss) income, which is reported on the income statement as consolidated net loss (income). The measure of segment assets is reported on the balance sheet as total consolidated assets.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval.

As such, the CODM uses cash forecast models in deciding how to invest into the life science segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss (income) is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment and in establishing management's compensation, along with cash forecast models.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025, and 2024:

	Years Ended December 31,	
	2025	2024
Operating Expenses:		
PMN310 development program costs	$ 30,226,059	$ 8,275,268
Other non-employee research and development costs	885,907	772,501
Employee costs	5,051,277	3,336,580
Other general and administrative costs	4,004,065	4,443,129
Net Operating Loss:	$ 40,167,308	$ 16,827,478
Other segment items[(a)]	(448,161)	(19,606,351)
Net Loss (Income):	$ 39,719,147	$ (2,778,873)
Reconciliation of Profit or Loss		
Adjustments and reconciling items	—	—
Consolidated Net Loss (Income):	$ 39,719,147	$ (2,778,873)

[(a)]Other segment items included in segment loss include changes in warrant liability, interest income, and interest expense

11. RELATED PARTY TRANSACTIONS

UBC Collaborative Research Agreement

In April 2016, the Company entered into a collaborative research agreement ("**CRA**") with the University of British Columbia ("**UBC**") and the Vancouver Coastal Health Authority in the amount of C$787,500, with the Company's Chief Scientific Officer, as principal investigator at the UBC. In January 2022, the UBC CRA was amended to extend the project for an additional three years, and in December 2024, for an additional 1 year. Aggregate funding under the agreement was increased to a total of C$5,830,000 through February 2026. During the years ended December 31, 2025 and 2024, the Company made cash payments of $428,860 and $587,000, respectively, and incurred costs of $573,187 and $584,226, respectively, which are included in research and development expenses in the accompanying consolidated statements of operations.

Neil Warma Employment Agreement

In October 2024, in connection with Mr. Neil Warma's appointment to the role of CEO, he entered into an employment agreement with the Company (the "**CEO Employment Agreement**") providing for an annual base salary of $500,000 and annual discretionary bonus with a target of 50% of his base salary. Mr. Warma was also provided (i) severance in the amount of 12-months' salary, a pro-rated annual bonus at target, acceleration of time-based stock options and standard continuing benefits in connection with a termination without cause and (ii) severance in the amount of the sum of 18-months' salary and a pro-rated annual bonus at target, acceleration of time-based stock options and standard continuing benefits in connection with a change in control of the Company.

In connection with his appointment, Mr. Warma was also granted (i) an option to purchase 45,765 of the Company's common shares (the "**Initial Award**") and (ii) an option to purchase 19,614 of the Company's common shares (the "**Performance Award**"). Per the Company's 2015 Stock Option Plan, the exercise price of each of the Initial Award and the Performance Award is $28.75 per share, the 5-day volume-weighted average price ("**VWAP**") as of October 8, 2024. The Initial Award is 25% vested upon grant with the remaining shares vesting ratably over thirty-six months. The Performance Award shall vest 25% on the date that the 10-day VWAP of the Company's common shares on the Nasdaq Capital Market exceeds three times the exercise price, with the remainder vesting ratably over the following thirty-six months. Refer to Note 8, Share-Based Compensation, for further discussion on the Performance Award.

12. COMMITMENTS AND CONTINGENCIES

Research, Development and License Agreements

The Company enters into research, development and license agreements with various parties in the ordinary course of business where the Company receives research services and rights to proprietary technologies. The agreements require compensation to be paid by the Company, typically, by a combination of the following:

- fees comprising amounts due initially on entering into the agreements and additional amounts due either on specified timelines or defined services to be provided;
- milestone payments that are dependent on products developed under the agreements proceeding toward specified plans of clinical trials and commercial development; and
- royalty payments calculated as a percentage of net sales, commencing on commercial sale of any product candidates developed from the technologies.

Milestone and royalty related amounts that may come due under various agreements are dependent on, among other factors, preclinical safety and efficacy, clinical trials, regulatory approvals and, ultimately, the successful development and commercial launch of a new drug, the outcomes and timings of which are uncertain. Amounts due per the various agreements for milestone payments will accrue once the occurrence of a milestone is likely. Amounts due as royalty payments will accrue as commercial revenues from the product are earned. Through December 31, 2025, no events have occurred that require accrual of any milestone or royalty related amounts.

UBC and the Vancouver Coastal Health Authority Agreement

In April 2016, the Company entered into a three-year, CRA with the UBC and the Vancouver Coastal Health Authority. The agreement was amended various times through November 2021. Refer to Note 11 Related Party Transactions.

UBC Agreement

In February 2009, the Company entered into an agreement with UBC to further the development and commercialization of certain technology developed, in part, by the Company's Chief Scientific Officer. The agreement was amended and restated in October 2015. Under the amended and restated agreement, the Company is committed to make royalty payments based on revenue earned from the licensed technology. An annual license fee is payable over the term of the agreement. The agreement remains effective unless terminated under the provisions of the agreement. The Company made annual license payments of C$25,000 during each of the years ended December 31, 2025 and 2024. Through December 31, 2025 no accruals for royalty payments have been made.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers

against liabilities that may arise by reason of their status or service as directors or officers. The Company currently has directors' and officers' insurance.

13. NET LOSS PER SHARE

Basic net earnings per share applicable to common stockholders is calculated by dividing net earnings applicable to common shareholders by the weighted average shares outstanding during the period, without consideration for common share equivalents. Diluted net earnings per share applicable to common shareholders is calculated by adjusting the weighted average shares outstanding for the dilutive effect of common share equivalents outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the calculation of dilutive net (loss) income per share applicable to common shareholders, stock options, and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net (loss) income per share applicable to common shareholders when their effect would be anti-dilutive or would not add additional Common Shares to the denominator of the calculation due to being out-of-the-money.

As of December 31, 2025 and 2024, respectively, 74,673 and 86,481 Pre-Funded Warrants to purchase common shares for little to no consideration, issued in connection with the August 2023 Private Placement and July 2024 Private Placement (see Note 6), were included in the basic and diluted net (loss) income per share calculation. The following table sets forth the computation of basic and diluted net loss (income) per share attributable to common shareholders:

	Years Ended December 31,	
	2025	2024
Numerator:		
Net (loss) income	$ (39,719,147)	$ 2,778,873
Denominator:		
Weighted-average shares outstanding used in computing net (loss) income per share attributable to common shareholders, basic and diluted	1,756,844	1,036,799
Effect of potentially dilutive securities:		
Warrants	—	20,882
Stock options	—	789
Diluted weighted-average common shares outstanding	1,756,844	1,058,469
Net (loss) income per share attributable to common shareholders, basic and diluted	$ (22.61)	$ 2.68
Diluted net (loss) income per share attributable to common shareholders	$ (22.61)	$ 2.63

The following outstanding potentially dilutive common shares equivalents were excluded from the computation of diluted net (loss) income per share for the periods presented because including them would have been antidilutive:

	Year Ended December 31,	
	2025	2024
Options issued and outstanding under stock option plan	180,827	142,978
Warrants	2,564,332	2,199,175
Deferred share units	42	42
Total	2,745,201	2,342,195

14. SUBSEQUENT EVENTS

On January 29, 2026, the Company completed a private placement for aggregate gross proceeds of $75.5 million to sell an aggregate of (i) 6,815,296 Common Shares, (ii) Common Share purchase warrants ("**Common Share**

Warrants") to purchase 6,915,296 Common Shares, (iii) Pre-Funded Warrants ("**Pre-Funded Warrants**") to purchase 100,000 Common Shares (collectively the "**January 2026 PIPE**"). 6,090,075 Common Shares and 6,090,075 Common Share Warrants were sold at a price of $10.77 for one Common Share and one Common Share Warrant. 100,000 Pre-Funded Warrants and 100,000 Common Share Warrants were sold at a price of $10.77 for one Pre-Funded Warrant and one Common Share Warrant, less an exercise price of $0.0001 per Pre-Funded Warrant. 725,221 Common Shares and 725,221 Common Share Warrants were sold to certain of our directors and management at a price of $12.13 for one Common Share and one Common Share Warrant.

The Common Share Warrants have an exercise price of $14.40, are exercisable immediately and will expire upon the earlier of (i) within 60 days of the Milestone Event (as defined below) or (ii) February 3, 2031. The Pre-Funded Warrants have an exercise price of $0.0001 per Pre-Funded Warrant, are immediately exercisable and will expire when exercised in full. For purposes of the foregoing, the "Milestone Event" means the public announcement via press release or the filing of a Current Report on Form 8-K of topline data from the cohorts treated with multiple ascending doses of PMN310. Fees and other expenses are currently not estimable by the Company, as they are still being determined.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure0

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2025.

Based on this evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective as of December 31, 2025.

Management's Annual 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 a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

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

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Remediation of Previously Identified Material Weakness

As previously disclosed in our 2024 Annual Report on Form 10-K, management identified a material weakness in the Company's internal control over financial reporting related to the fair value calculations related to certain financial instruments, specifically the calculation over the fair value of the July 2024 PIPE Warrant Liability. the Company did not design and maintain effective controls over the review of certain fair value calculations, which could have resulted in a material misstatement of the Company's financial statements that would not have been prevented or detected on a timely basis.

Remediation of Material Weakness

To address the material weakness described above, the Company implemented a number of measures to remediate the material weakness, including enhancing review controls over the calculation of the fair value of its financial instruments, engaging qualified third-party specialists to assist in the valuation when necessary and improving the documentation and review of management's accounting analyses.

These remediation measures were implemented and have been in operation for a sufficient period of time during the year ended December 31, 2025. Management has performed testing of the design and operation of these controls and based on the results of such testing concluded that the controls are operating effectively.

Accordingly, management concluded that the material weakness described above has been remediated as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

Except for the remediation measures in connection with the material weakness described above, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, that occurred during the twelve months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

Item 9B. Other Information

During the twelve months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 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 will be contained in our 2026 Proxy Statement, to be filed with the SEC not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated in this report by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code of Business Conduct and Ethics is posted on our website at https://www.promisneurosciences.com/investors/corporate-governance/governance-documents.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of Nasdaq, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

The Company has an insider trading policy governing the purchase, sale and other dispositions of the Company's securities that applies to all Company's directors, officers, employees and other covered persons. The Company believes that its insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. It is also the policy of the Company to comply with all insider trading laws and regulations. A copy of the Company's insider trading policy is filed as Exhibit 19.1 to this Form 10-K.

Item 11. Executive Compensation

The information required by this item will be contained in our 2026 Proxy Statement, to be filed with the SEC not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated in this report by reference.

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

The information required by this item will be contained in our 2026 Proxy Statement, to be filed with the SEC not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated in this report by reference.

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

The information required by this item will be contained in our 2026 Proxy Statement, to be filed with the SEC not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated in this report by reference.

Item 14. Principal Accountant's Fees and Services

The information required by this item will be contained in our 2026 Proxy Statement, to be filed with the SEC not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated in this report by reference.

Our independent public accounting firm is Baker Tilly US, LLP, Tewksbury, Massachusetts, PCAOB Auditor ID 23.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

Not applicable

EXHIBIT INDEX

Exhibit Number	Description
3.1	Articles. (incorporated herein by reference to Exhibit 3.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
3.1.1	Certificate of Amendment to the Articles dated July 8, 2015. (incorporated herein by reference to Exhibit 3.1.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
3.1.2	Certificate of Amendment to the Articles dated June 17, 2022. (incorporated herein by reference to Exhibit 3.1.2 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
3.1.3	Certificate of Amendment to the Articles dated June 21, 2022. (incorporated herein by reference to Exhibit 3.1.3 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
3.1.4	Articles of Continuance. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 14, 2023).
3.1.5	Certificate of Amendment to the Articles dated December 4, 2023. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 8, 2023).
3.1.6	Certificate of Amendment to the Articles dated November 28, 2025. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 24, 2025).
3.2	Amended and Restated By-law No. 1. (incorporated herein by reference to Exhibit 3.2 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
3.2.1	By-law No. 2. (incorporated herein by reference to Exhibit 3.2.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
3.2.2	Amended and Restated By-law No. 1. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 14, 2023).
3.2.3	Amended and Restated By-law No. 2. (incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 14, 2023).
4.1	Form of Amended and Restated Unsecured Convertible Debenture dated June 17, 2022. (incorporated herein by reference to Exhibit 4.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
4.2	Form of PIPE Warrant. (incorporated herein by reference to Exhibit 4.2 to ProMIS' Current Report on Form 8-K filed October 17, 2022).
4.3	Form of Placement Agent Warrant. (incorporated herein by reference to Exhibit 4.3 to ProMIS' Current Report on Form 8-K filed October 17, 2022).
4.4*	Description of the Registrant's Securities
4.5	Form of Warrant. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 22, 2023).
4.6	Form of Pre-Funded Warrant. (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 22, 2023).
4.7	Form of Pre-Funded Warrant. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 26, 2024).
4.8	Form of Tranche A Warrant. (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 26, 2024).
4.9	Form of Tranche B Warrant. (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 26, 2024).
4.10	Form of Tranche C Warrant. (incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 26, 2024).
4.11	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 22, 2025).
4.12	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 22, 2025).
4.13	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 28, 2025).
4.14	Form of Common Share Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed January 30, 2026).
4.15	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed January 30, 2026).
10.1+	Joint Venture Agreement dated July 7, 2020 by and between ProMIS Neurosciences Inc. and BC Neuroimmunology Lab Inc. (incorporated herein by reference to Exhibit 10.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).

10.2+	Joint Venture Agreement dated July 8, 2020 by and between ProMIS Neurosciences Inc. and BC Neuroimmunology Lab Inc. (incorporated herein by reference to Exhibit 10.2 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.3+	Collaborative Research Agreement by and between The University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc. effective April 1, 2016. (incorporated herein by reference to Exhibit 10.3 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.3.1+	Amendment No. 1 dated February 13, 2017 to the Collaborative Research Agreement by and between The University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc. (incorporated herein by reference to Exhibit 10.3.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.3.2+	Amendment No. 2 dated July 5, 2018 to the Collaborative Research Agreement by and between The University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc. (incorporated herein by reference to Exhibit 10.3.2 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.3.3+	Amendment No. 3 dated February 13, 2019 to the Collaborative Research Agreement by and between The University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc. (incorporated herein by reference to Exhibit 10.3.3 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.3.4+	Amendment No. 4 dated September 9, 2019 to the Collaborative Research Agreement by and between The University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc. (incorporated herein by reference to Exhibit 10.3.4 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.3.5+	Amendment No. 5 dated January 11, 2022 to the Collaborative Research Agreement by and between the University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc.
10.3.6+	Memo dated November 24, 2021 confirming increase of ProMIS Neurosciences Inc. SRA with the University of British Columbia.
10.4+	Amended and Restated License Agreement dated October 6, 2015 by and between The University of British Columbia and ProMIS Neurosciences Inc. (incorporated herein by reference to Exhibit 10.4 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.5+	License Agreement dated August 3, 2006 by and between Amorfix Life Sciences Ltd. and an Affiliate of Biogen Idec Inc. (incorporated herein by reference to Exhibit 10.5 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.6+	Exclusive License Agreement dated July 14, 2010 by and between Amorfix Life Sciences Ltd. and Biogen Idec MA Inc. (incorporated herein by reference to Exhibit 10.6 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.7+	License Agreement dated April 4, 2006 by and between University Health Network and Amorfix Life Sciences Inc. (incorporated herein by reference to Exhibit 10.7 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.7.1	Amendment dated July 13, 2006 to the License Agreement dated April 4, 2006 by and between University Health Network and Amorfix Life Sciences Inc. (incorporated herein by reference to Exhibit 10.7.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.7.2+	Amendment No. 2 dated July 11, 2007 to the License Agreement dated April 4, 2006 by and between University Health Network and Amorfix Life Sciences Ltd. (incorporated herein by reference to Exhibit 10.7.2 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.7.3+	Amendment No. 3 dated November 4, 2013 to the to the License Agreement dated April 4, 2006 by and between University Health Network and Amorfix Life Sciences Ltd. (incorporated herein by reference to Exhibit 10.7.3 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.9†+	Advisory Consulting Agreement dated May 26, 2021 by and between ProMIS Neurosciences Inc. and David Wishart. (incorporated herein by reference to Exhibit 10.9 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.10†+	Consulting and Advisory Agreement dated March 1, 2005 by and between Amorfix Life Sciences Ltd. And Neil Cashman. (incorporated herein by reference to Exhibit 10.10 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).

10.11†+	Consulting Agreement dated June 29, 2015 by and between Amorfix Life Sciences Ltd. and Virtua, LLC. (incorporated herein by reference to Exhibit 10.11 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.12†+	Consulting Agreement dated October 17, 2016 by and between ProMIS Neurosciences Inc. and Danforth Advisors, LLC. (incorporated herein by reference to Exhibit 10.12 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.12.1†+	Amendment No. 1 dated March 27, 2017 to Consulting Agreement dated October 17, 2016 by and between ProMIS Neurosciences Inc. and Danforth Advisors, LLC. (incorporated herein by reference to Exhibit 10.12.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.12.2†	Amendment No. 2 dated December 12, 2017 to Consulting Agreement dated October 17, 2016 by and between ProMIS Neurosciences Inc. and Danforth Advisors, LLC. (incorporated herein by reference to Exhibit 10.12.2 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.12.3†	Amendment No. 3 dated August 28, 2018 to Consulting Agreement dated October 17, 2016 by and between ProMIS Neurosciences Inc. and Danforth Advisors, LLC. (incorporated herein by reference to Exhibit 10.12.3 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.12.4†+	Amendment No. 4 dated March 27, 2017 to Consulting Agreement dated October 17, 2016 by and between ProMIS Neurosciences Inc. and Danforth Advisors, LLC. (incorporated herein by reference to Exhibit 10.12.4 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.13	Form of Finder's Warrant Certificate dated April 30, 2018. (incorporated herein by reference to Exhibit 10.13 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.14	Form of Non-US Warrant Certificate dated April 30, 2018. (incorporated herein by reference to Exhibit 10.14 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.15	Form of Employee Stock Option Commitment. (incorporated herein by reference to Exhibit 10.15 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.16+	Form of Unit Subscription Agreement for Non-U.S. Subscribers dated February 25, 2020. (incorporated herein by reference to Exhibit 10.16 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.17+	Form of Unit Subscription Agreement for Non-U.S. Subscribers dated June 17, 2019. (incorporated herein by reference to Exhibit 10.17 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.18+	Form of Unit Subscription Agreement for U.S. Subscribers dated November 27, 2018. (incorporated herein by reference to Exhibit 10.18 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.19+	Form of Unit Subscription Agreement for U.S. Subscribers dated October 21, 2019. (incorporated herein by reference to Exhibit 10.19 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.20+	Form of Unit Subscription Agreement for U.S. Subscribers dated April 13, 2018. (incorporated herein by reference to Exhibit 10.20 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.21+	Form of Unit Subscription Agreement for Non-U.S. Subscribers dated April 13, 2018. (incorporated herein by reference to Exhibit 10.21 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.22+	Form of Unit Subscription Agreement for Non-U.S. Subscribers dated November 27, 2018. (incorporated herein by reference to Exhibit 10.22 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.23+	Form of Unit Subscription Agreement for Non-U.S. Subscribers dated October 21, 2019. (incorporated herein by reference to Exhibit 10.23 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.24+	Form of Finder's Warrant Certificate dated November 2020. (incorporated herein by reference to Exhibit 10.24 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.25+	Form of Non-U.S. Finder's Warrant Certificate dated January 2019. (incorporated herein by reference to Exhibit 10.25 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.26+	Form of Non-U.S. Warrant Certificate dated January 2019. (incorporated herein by reference to Exhibit 10.26 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.27+	Form of Non-U.S. Warrant Certificate dated June 2019. (incorporated herein by reference to Exhibit 10.27 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.28+	Form of U.S. Warrant Certificate dated January 2019. (incorporated herein by reference to Exhibit 10.28 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.29+	Form of U.S. Warrant Certificate dated November 2020. (incorporated herein by reference to Exhibit 10.29 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.30	Form of Special Warrant Certificate dated November 4, 2020. (incorporated herein by reference to Exhibit 10.30 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.31	Form of U.S. Special Warrant Certificate dated November 4, 2020. (incorporated herein by reference to Exhibit 10.31 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.32+	Form of Warrant Certificate dated November 2020. (incorporated herein by reference to Exhibit 10.32 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).

10.33+	Technology License Agreement dated February 1, 2006 by and between Dr. Neil Roy Cashman and Amorfix Life Sciences Ltd. (incorporated herein by reference to Exhibit 10.33 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.34+	Service Agreement dated September 1, 2020 by and between The University of Saskatchewan and ProMIS Neurosciences Inc. (incorporated herein by reference to Exhibit 10.34 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.35+	Assignment Agreement dated February 18, 2005 by and between Neil R. Cashman and Marty Lehto and the Governing Council of the University of Toronto and Amorfix Life Sciences Ltd. (incorporated herein by reference to Exhibit 10.35 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.35.1	Amendment Agreement dated April 1, 2005 to the Assignment Agreement dated February 18, 2005 by and between Neil R. Cashman and Marty Lehto and the Governing Council of the University of Toronto and Amorfix Life Sciences Ltd. (incorporated herein by reference to Exhibit 10.35.1 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.37†+	Executive Employment Agreement of Gavin Malenfant dated December 31, 2021. (incorporated herein by reference to Exhibit 10.37 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.38†	ProMIS Neurosciences Inc. 2015 Stock Option Plan.
10.39†	Amorfix Life Sciences Ltd. Deferred Share Unit Plan for Canadian Senior Officers. (incorporated herein by reference to Exhibit 10.39 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.40	Form of Non-U.S. Finder's Warrant Certificate dated November 2019. (incorporated herein by reference to Exhibit 10.40 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.41	Form of Non-U.S. Warrant Certificate dated November 2019. (incorporated herein by reference to Exhibit 10.41 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.42	Form of U.S. Warrant Certificate dated November 2019. (incorporated herein by reference to Exhibit 10.42 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.43	Form of Non-U.S. Warrant Certificate dated November 2020. (incorporated herein by reference to Exhibit 10.43 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.44	Form of Broker Warrant dated August 2021. (incorporated herein by reference to Exhibit 10.44 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.45	Form of Non-U.S. Warrant Certificate dated August 2021. (incorporated herein by reference to Exhibit 10.45 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.46	Form of U.S. Warrant Certificate dated August 2021. (incorporated herein by reference to Exhibit 10.46 to ProMIS' Form 10 Registration Statement filed June 22, 2022, as amended).
10.47*†+	Employment agreement by and between ProMIS Neurosciences Inc. and Larry Altstiel. Effective March 1, 2025.
10.48	Strategic Services Agreement, dated September 12, 2022, by and between ProMIS Neurosciences Inc. and Eugene Williams, effective September 19, 2022. (incorporated herein by reference to Exhibit 10.48 to ProMIS' Current Report on Form 8-K filed September 13, 2022).
10.50+	Unit Purchase Agreement by and between ProMIS Neurosciences Inc. and various investors (incorporated herein by reference to Exhibit 10.50 to ProMIS' Registration Statement on Form S-1 filed on November 1, 2022, as amended).
10.51	Registration Rights Agreement by and between ProMIS Neurosciences Inc. and various investors (incorporated herein by reference to Exhibit 10.51 to ProMIS' Registration Statement on Form S-1 filed on November 1, 2022, as amended).
10.52†	Executive Employment Agreement of Neil Cashman dated January 21, 2022, effective February 1, 2022 (incorporated herein by reference to Exhibit 10.52 to ProMIS' Registration Statement on Form S-1 filed on November 1, 2022, as amended).
10.53	Amended and Restated Placement Agent Agreement, dated September 22, 2022, by and between ProMIS Neurosciences Inc. and Ceros Financial Services, Inc. (incorporated herein by reference to Exhibit 1.1 to ProMIS' Current Report on Form 8-K filed October 17, 2022).
10.54	Amendment No. 1 to Amended and Restated Placement Agent Agreement, dated October 5, 2022 by and between ProMIS Neurosciences Inc. and Ceros Financial Services, Inc. (incorporated herein by reference to Exhibit 1.2 to ProMIS' Current Report on Form 8-K filed October 17, 2022).
10.55	Form of Unit Purchase Agreement. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 22, 2023).
10.56	Form of Registration Rights Agreement. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 22, 2023).
10.57	Share Exchange Agreement between the Company and holders of Series 1 Preferred Shares dated December 4, 2023. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 8, 2023).

10.59†	Employment Agreement with Neil Warma, dated October 8, 2024. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 10, 2024).
10.60	Form of Indemnification Agreement. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 10, 2024).
10.61	Form of Unit Purchase Agreement. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 26, 2024).
10.62	Form of Registration Rights Agreement. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 26, 2024).
10.63	Amendment No. 6 dated December 2, 2024 to the Collaborative Research Agreement by and between the University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities Exchange Commission on May 12, 2025)
10.64	Employment agreement by and between ProMIS Neurosciences Inc. and Larry Altstiel. Effective March 1, 2025 (incorporated herein by reference to Exhibit 10.47 to ProMIS' Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 31, 2025).
10.65	Separation agreement by and between ProMIS Neurosciences Inc. and Gavin Malenfant. Effective February 14, 2025 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities Exchange Commission on May 12, 2025).
10.66	ProMIS Neuroscience Inc. 2025 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2025).
10.67	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 22, 2025).
10.68	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 28, 2025).
10.69	Amended and Restated Employment Agreement with Neil Cashman (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 30, 2025).
10.70	Amended and Restated Employment Agreement with Johanne Kaplan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2025).
10.71	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 22, 2025).
10.72	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 28, 2025).
10.73	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 30, 2026).
10.74	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 30, 2026).
10.75*	Amendment No. 7 dated February 12, 2026 to the Collaborative Research Agreement by and between the University of British Columbia and Provincial Health Services Authority (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) and ProMIS Neurosciences Inc.
16.1	Letter from PricewaterhouseCoopers LLP dated July 28, 2022 to the Securities and Exchange Commission regarding change in certifying accountant. (incorporated herein by reference to Exhibit 16.1 to ProMIS' Current Report on Form 8-K filed July 29, 2022).
19.1	Insider trading policy adopted March 27, 2025 (incorporated herein by reference to Exhibit 19.1 to ProMIS' Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 31, 2025).
21.1*	List of Subsidiaries of the Registrant
23.1*	Consent of Baker Tilly US, LLP, independent registered public accounting firm
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e)
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e)
32*	Certification of Chief Executive Officer and Chief Financial Officer of Periodic Report Pursuant to 18 U.S.C. Section 1350
97.1	ProMIS Neurosciences Inc. Clawback Policy. (incorporated herein by reference to Exhibit 97.1 to ProMIS' 10-K filed April 1, 2024).
101.INS*	Inline 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*	Inline XBRL Taxonomy Extension Schema Document

101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101*).

† Management Contract or compensatory plan or arrangement.

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

* Filed herewith.

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, on March 25, 2026.

PROMIS NEUROSCIENCES INC.

By: /s/ Neil Warma
Neil Warma
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 25, 2026 by the following persons on behalf of the registrant and in the capacities indicated:

Signature	Title
/s/ Neil Warma Neil Warma	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Daniel Geffken Daniel Geffken	Chief Financial Officer (Principal Financial Officer)
/s/ Max Milbury Max Milbury	Vice President, Finance (Principal Accounting Officer)
/s/ Eugene Williams Eugene Williams	Director
/s/ Neil Cashman Neil Cashman	Chief Science Officer and Director
/s/ Patrick Kirwin Patrick Kirwin	Director
/s/ Joshua Mandel-Brehm Joshua Mandel-Brehm	Director
/s/ Maggie Shafmaster Maggie Shafmaster	Director
/s/ William Wyman William Wyman	Director
/s/ Slanix Paul Alex Slanix Paul Alex	Director

Exhibit 4.4

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

The following description of the capital stock of ProMIS Neurosciences Inc. (the "Company") is intended as a summary only and therefore is not a complete description of the Company's capital stock. This description is based upon, and is qualified by reference to, the Articles of the Company, as amended (the "Articles"), and its Bylaws, as amended (the "Bylaws", together with the Articles, the "Constating Documents"), which are filed as exhibits to the Annual Report on Form 10-K, of which this Exhibit 4.4 is a part.

General

The Company's authorized share capital consists of an unlimited number of common shares, no par value (the "Common Shares"), and an unlimited number of preferred shares, no par value, issuable in series (the "Preferred Shares").

Common Shares

Voting Rights

The holders of Common Shares shall be entitled to receive notice of all meetings of shareholders, and to attend, vote and speak at such meetings, except those meetings at which only holders of another specified class or series of shares of the Company are entitled to vote separately as a class or series. A quorum for a meeting of Shareholders shall be two shareholders, or two proxyholders representing shareholders, or any combination thereof, holding not less than thirty-three and one-third percent (33 1/3%) of the issued shares entitled to be voted at the meeting. On all matters upon which holders of shares are entitled to vote, each Common Share is entitled to one vote per Common Share. Unless a different majority is required by law or the Constating Documents, resolutions to be approved by holders of shares require approval by a simple majority of the total number of votes of all shares cast at a meeting of Shareholders at which a quorum is present.

Dividend Rights

There are no restrictions in the Company's Articles or elsewhere, which would prevent the Company from paying dividends. No dividends have been declared or paid on the Common Shares of the Company in the last five fiscal years, and it is not expected that dividends will be declared or paid in the immediate or foreseeable future. Consequently, to date there have been no distributions made by the Company. The policy of the Board of Directors of the Company (the "Board") is to reinvest all available funds in operations. The Board will reassess this policy from time to time. Any decision to pay dividends on the Common Shares of the Company will be made by the Board based on the assessment of, among other factors, earnings, capital requirements and the operating and financial condition of the Company, subject to any rights of the holders of Preferred Shares.

Liquidation Rights

In the event of the liquidation, dissolution or winding-up of the Company or any other distribution of the Company's assets for the purpose of winding up the Company's affairs, after the payment of dividends declared but unpaid, the holders of Common Shares shall be entitled *pari passu* to receive any remaining property of the Company.

Preemptive, Redemption and Other Rights

Holders of Common Shares do not have any preemptive, conversion, sinking fund or redemption rights. The rights, preferences and privileges of the holders of the Company's Common Shares are subject to, and may be adversely affected by, the rights of the holders of shares of any series of the Company's Preferred Shares that currently exist or that we may designate and issue in the future.

Preferred Shares

The Preferred Shares of the Company may be issued in one or more series and the directors are authorized to fix the number of Preferred Shares in each series and to determine the designation, rights, privileges, restrictions and conditions attached to the Preferred Shares of each series. The special rights or restrictions which the directors may create, define or attach to any series of Preferred Shares may allow the directors to declare dividends with respect to the Common Shares only or with respect to any series of Preferred Shares only or with respect to any combination of two or more such classes or series of classes. Where Preferred Shares or one or more series of Preferred Shares are entitled to cumulative dividends, and where cumulative dividends in respect of the Preferred Shares or a series of Preferred Shares are not paid in full, the shares of all series of Preferred Shares entitled to cumulative dividends shall participate ratably in respect of accumulated dividends in accordance with the amounts that would be payable on those shares if all the accumulated dividends were pain in full.

The Company does not currently have any outstanding Preferred Shares.

Registration Rights

Certain of the Company's holders are entitled to piggyback registration rights provided under the terms of a registration rights agreement between the Company and certain holders of the Company's Common Shares, entered into in connection with PIPE Offerings to effect the filing of resale Registration Statements. We are not required to register any securities pursuant to such registration rights agreement if such shares are eligible for resale pursuant to Rule 144 or that are the subject of a then-effective registration statement.

Anti-Takeover effects of the Company's Constating Documents

Provisions of the Company's Constating Documents and the Business Corporations Act (Ontario) (the "OBCA") may discourage, delay or prevent a merger or acquisition that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their Common Shares, and may also frustrate or prevent any attempt by shareholders to change the direction or management. For example, these provisions:

- require a 66 2/3% majority of shareholder votes cast in favor of a resolution to effect various amendments to the articles;
- require that in the event of shareholders of the Company vote via written resolution, that such resolution must be signed by all shareholders of the Company entitled to vote on that resolution;
- establish advance notice requirements for nominations for election to the Board at any annual or special meeting of shareholders of the Company; and
- any transaction in which a third party seeks to acquire the Company's voting securities or equity securities that would result in the acquiror holding greater than 20% of the securities of that class may be governed by NI 62-104 promulgated by the Canadian Securities Administrators ("CSA"), as more fully described below.

Advance Notice Requirements

Under our advance notice provisions in our Bylaws, a shareholder wishing to nominate a director would be required to provide the Company with notice, in a prescribed form and within prescribed time periods. These time periods include, (1) in the case of an annual meeting of shareholders (including annual and special meetings), not less than 30 days prior to the date of the annual meeting of shareholders; provided that if the first public announcement of the date of the annual meeting of shareholders, which we refer to as the notice date, is less than 40 days before the meeting date, not later than the close of business on the 10th day following the notice date, and (2) in the case of a special meeting (which is not also an annual meeting) of shareholders called for any purpose which includes electing directors, not later than the close of business on the 15th day following the notice date.

Takeover Bid Provisions of Canadian Securities Law

All provinces of Canada have adopted NI 62-104 and related forms to harmonize and consolidate take-over bid and issuer bid regimes nationally. The CSA have also issued National Policy 62-203 entitled "Take-Over Bids and Issuer Bids" (the "National Policy") which contains regulatory guidance on the interpretation and application of NI 62-104 and on the conduct of parties involved in a bid. The National Policy and NI 62-104 are collectively referred to as the "Bid Regime." The National Policy does not have the force of law, but is an indication by the CSA of what the intentions and desires of the regulators are in the areas covered by their policies.

A "take-over bid" or "bid" is an offer to acquire outstanding voting or equity securities of a class made to any person who is in one of the provinces of Canada or to any securityholder of an offeree issuer whose last address as shown on the books of a target is in such province, where the securities subject to the offer to acquire, together with the securities "beneficially owned" by the offeror, or any other person acting jointly or in concert with the offeror, constitute in the aggregate 20% or more of the outstanding securities of that class of securities at the date of the offer to acquire. For the purposes of the Bid Regime, a security is deemed to be "beneficially owned" by an offeror as of a specific date if the offeror is the beneficial owner of a security convertible into the security within 60 days following that date, or has a right or obligation permitting or requiring the offeror, whether or not on conditions, to acquire beneficial ownership of the security within 60 days by a single transaction or a series of linked transactions.

Offerors are also subject to early warning requirements, where an offeror who acquires "beneficial ownership of", or control or direction over, voting or equity securities of any class of a reporting issuer or securities convertible into, voting or equity securities of any class of a target that, together with the offeror's securities, would constitute 10% or more of the outstanding securities of that class must promptly publicly issue and file a news release containing certain prescribed information, and, within two business days, file an early warning report containing substantially the same information as is contained in the news release.

In addition, where an offeror is required to file an early warning report or a further report as described and the offeror acquires or disposes of beneficial ownership of, or the power to exercise control or direction over, an additional 2% or more of the outstanding securities of the class, or disposes of beneficial ownership of outstanding securities of the class below 10%, the offeror must issue an additional press release and file a new early warning report. Any change in material fact in a previously filed early warning report also triggers the issuance and filing of a new press release and early warning report. During the period commencing on the occurrence of an event in respect of which an early warning report is required and terminating on the expiry of one business day from the date that the early warning report is filed, the offeror may not acquire or offer to acquire beneficial ownership of any securities of the class in respect of which the early warning report was required to be filed or any securities convertible into securities of that class. This requirement does not apply to an offeror that has beneficial ownership of, or control or direction over, securities that comprise 20% of more of the outstanding securities of the class.

Related party transactions, issuer bids and insider bids are subject to additional regulation that may differ depending on the particular jurisdiction of Canada in which it occurs. For additional information on Shareholder Nominations and Proposals, Amendments to Constating Documents, Votes on Mergers, Consolidations and Sales of Assets, Transactions with Directors and Officers and other provisions, please see the section below entitled "*Comparison of Canadian and Delaware Law*."

Comparison of Canadian Law and Delaware Law

There are significant differences between the OBCA and the Delaware General Corporate Law (the "DGCL") which governs companies incorporated in the State of Delaware, including:

Delaware	Canada
Capital Structure	
Under the DGCL, the certificate of incorporation must set forth the total number of shares of stock which the corporation shall have authority to issue and the par value of each of such shares, or a statement that the shares are to be without par value.	Under the OBCA, the articles of incorporation may but are not required to set forth the maximum number of shares that the corporation is authorized to issue.
Dividends	
The DGCL generally provides that, subject to certain restrictions, the directors of a corporation may declare and pay dividends upon the shares of its capital stock either out of the corporation's surplus or, if there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. Further, the holders of preferred or special stock of any class or series may be entitled to receive dividends at such rates, on such conditions and at such times as stated in the certificate of incorporation.	Under the OBCA, dividends may be declared on the common shares at the discretion of the board of directors. Any dividends declared shall be subject to the rights, if any, of shareholders holding shares with special rights as to dividends. Dividends may not be declared if there are reasonable grounds for believing that the corporation is, or would after the payment be, unable to pay its liabilities as they become due or the realizable value of the corporation's assets would thereby be less than the aggregate of its liabilities and stated capital of all classes.
Number and Election of Directors	
Under the DGCL, the board of directors must consist of at least one person, and the number of directors is generally fixed by, or in the manner provided in, the by laws of the corporation, unless the certificate of incorporation fixes the number of directors, in which case a change in the number of directors shall be made only by amendment of the certificate. The board of directors may be divided into three classes of directors, with one-third of each class subject to election by the stockholder each year after such classification becomes effective.	Under the OBCA, an offering corporation shall have no fewer than three individuals on the board of directors and at least one third shall not be officers or employees of the corporation or its affiliates. The articles of incorporation will commonly set out the number of initial directors and, if applicable, the minimum and maximum number of directors of the corporation. The shareholders may amend the articles to increase or decrease the number of directors or the minimum or maximum number of directors. In the case of an offering corporation, shareholders may by ordinary resolution elect directors to hold office for a term ending not later than the close of the third annual meeting of shareholders following the election. A director that is not elected for an expressly stated term shall cease to hold office at the close of the first annual meeting of shareholders following his or her election.

Delaware	Canada
Removal of Directors	
Under the DGCL, any or all directors may be removed with or without cause by the holders of a majority of shares entitled to vote at an election of directors unless the certificate of incorporation otherwise provides or in certain other circumstances if the corporation has cumulative voting.	Under the OBCA, the shareholders of a corporation may by ordinary resolution remove any director or directors from office. If the holders of any class or series of shares of a corporation have an exclusive right to elect one or more directors, a director so elected may only be removed by an ordinary resolution at a meeting of the shareholders of that class or series.
Vacancies on the Board of Directors	
Under the DGCL, vacancies and newly created directorships resulting from an increase in the authorized number of directors, may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.	Under the OBCA, vacancies on the board may be filled by a quorum of directors, except a vacancy resulting from an increase in the number of directors (otherwise than in accordance with the provisions under the OBCA on the appointment of directors subsequent to an annual meeting) or the maximum number of directors or a failure to elect the number directors required to be elected at any meeting of shareholders. If there is not a quorum of directors or if there has been a failure to elect the number of directors required by the articles or by the OBCA, the directors then in office shall forthwith call a special meeting of shareholders to fill the vacancy and, if they fail to call a meeting or if there are no directors then in office, the meeting may be called by any shareholder.
Qualifications of Directors	
Under the DGCL, directors are not required to be residents of Delaware or the United States. The certificate of incorporation or by-laws may prescribe other qualifications for directors.	Under the OBCA, there is no residency requirement for directors. The articles of incorporation may prescribe other qualifications for directors.
Board of Director Quorum and Vote Requirements	
Under the DGCL, a majority of the total number of directors shall constitute a quorum for the transaction of business unless the certificate or by-laws require a greater number. The by-laws may lower the number required for a quorum to one-third the number of directors, but no less.	Under the OBCA, subject to the articles or by-laws, a majority of the number of directors or minimum number of directors required by the articles constitutes a quorum at any meeting of directors. Where a corporation has fewer than three directors, all directors must be present at any meeting of directors to constitute a quorum. Subject to the articles or by-laws, where there is at least one vacancy in the board of directors, the remaining directors may exercise all the powers of the board so long as a quorum of the board remains in office.

Delaware	Canada
Transactions with Directors and Officers	
The DGCL generally provides that no transaction between a corporation and one or more of its directors or officers, or between a corporation and any other corporation or other organization in which one or more of its directors or officers, are directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the board or committee which authorizes the transaction, or solely because any such director's or officer's votes are counted for such purpose, if (i) the material facts as to the director's or officer's interest and as to the transaction are known to the board of directors or the committee, and the board or committee in good faith authorizes the transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum (ii) the material facts as to the director's or officer's interest and as to the transaction are disclosed or are known to the stockholders entitled to vote thereon, and the transaction is specifically approved in good faith by vote of the stockholders; or (iii) the transaction is fair as to the corporation as of the time it is authorized, approved or ratified, by the board of directors, a committee or the stockholders.	Under the OBCA, a director or an officer of a corporation who (i) is a party to a material contract or transaction or proposed material contract or transaction with the corporation; or (ii) is a director or an officer of, or has a material interest in, any person who is a party to a material contract or transaction or proposed material contract or transaction with the corporation, shall disclose in writing to the corporation or request to have entered in the minutes of meetings of directors the nature and extent of his or her interest. Directors with a conflict of interest shall not attend any part of a meeting of directors during which that particular contract or transaction is discussed and shall not vote on any resolution to approve the contract or transaction unless the contract or transaction is one relating primarily to his or her remuneration as a director of the corporation or an affiliate, one for indemnity or insurance under the OBCA or one with an affiliate.
Limitation on Liability of Directors and Officers	
The DGCL permits a corporation to include a provision in its certificate of incorporation eliminating or limiting the personal liability of a director or officer to the corporation or its stockholders for monetary damages for a breach of the director's or officer's fiduciary duty as a director or officer, except for liability: ● for breach of the director's or officer's duty of loyalty to the corporation or its stockholders; ● for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of the law; ● for directors, under Section 174 of the DGCL, which concerns unlawful payment of dividends, stock purchases or redemptions; or ● for any transaction from which the director or officer derived an improper personal benefit.	No provision in a contract, the articles, the by-laws or a resolution may relieve a director or officer from the duty to act in accordance with the OBCA or the regulations or relieve him or her from liability for a breach thereof.

Delaware	Canada
Indemnification of Directors and Officers	
Under the DGCL, a corporation may indemnify any person who is made a party to any third-party action, suit or proceeding on account of being a director, officer, employee or agent of the corporation (or was serving at the request of the corporation in such capacity for another corporation, partnership, joint venture, trust or other enterprise) against expenses, including attorney's fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with the action, suit or proceeding through, among other things, a majority vote of a quorum consisting of directors who were not parties to the suit or proceeding, if the person: ● acted in good faith and in a manner he or she reasonably believed to be; ● in or not opposed to the best interests of the corporation; ● or, in some circumstances, at least not opposed to its best interests; and ● in a criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The DGCL permits indemnification for derivative suits against expenses (including legal fees) if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and only if the person is not found liable, unless a court determines the person is fairly and reasonably entitled to the indemnification.	Under the OBCA, a corporation may indemnify a director or officer of the corporation, a former director or officer of the corporation or another individual who acts or acted at the corporation's request as a director or officer, or an individual acting in a similar capacity, of another entity, against all costs, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by the individual in respect of any civil, criminal, administrative, investigative or other proceeding in which the individual is involved because of that association with the corporation or other entity. A corporation shall not indemnify an individual unless the individual (i) acted honestly and in good faith with a view to the best interests of the corporation (or, as the case may be, to the best interests of the other entity for which the individual acted as a director or officer or in a similar capacity at the corporation's request); and (ii) in the case of a criminal or administrative action or proceeding that is enforced by a monetary penalty, the individual had reasonable grounds for believing that the individual's conduct was lawful. An individual is entitled to indemnification if he or she fulfills the conditions above and was not judged by the court or other competent authority to have committed any fault or omitted to do anything that the individual ought to have done. The OBCA also permits indemnification for derivative suits with the approval of the court.
Call and Notice of Stockholder Meetings	
Under the DGCL, an annual or special stockholder meeting is held on such date, at such time and at such place as may be designated by the board of directors or any other person authorized to call such meeting under the corporation's certificate of incorporation or by-laws. If an annual meeting for election of directors is not held on the date designated or an action by written consent to elect directors in lieu of an annual meeting has not been taken within 30 days after the date designated for the annual meeting, or if no date has been designated, for a period of 13 months after the later of the last annual meeting or the last action by written consent to elect directors in lieu of an annual meeting, the Delaware Court of Chancery may summarily order a meeting to be held upon the application of any stockholder or director. Special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the by-laws.	Under the OBCA, the directors are required to call an annual meeting of shareholders not later than 18 months after the corporation comes into existence, and subsequently, not later than 15 months after holding the last preceding annual meeting. Subject to the articles and any unanimous shareholder agreement, a meeting of shareholders shall be held at such place in or outside Ontario as the directors determine or, in the absence of such a determination, at the place where the registered office of the corporation is located. A meeting held by telephone or electronic means shall be deemed to be held at the place where the registered office of the corporation is located. The directors may at any time call a special meeting of the shareholders. The holders of not less than five per cent of the issued shares of a corporation that carry the right to vote at a meeting may requisition the directors to call a meeting of shareholders for the purposes stated in the requisition.

Delaware	Canada
Stockholder Action by Written Consent	
Under the DGCL, a majority of the stockholders of a corporation may act by written consent without a meeting unless such action is prohibited by the corporation's certificate of incorporation.	Under the OBCA, shareholders may act by written resolution signed by all the shareholders entitled to vote on that resolution at a meeting of shareholders.
Stockholder Nominations and Proposals	
Under the DGCL, the by-laws of a corporation may include provisions respecting the nomination of directors or proposals by stockholders, including requirements for advance notice to the corporation.	Under the OBCA, a registered holder or beneficial owner of shares that are entitled to be voted at a meeting of shareholders may submit to the corporation notice of any matter that the person proposes to raise at the meeting (a "proposal") and discuss at the meeting any matter in respect of which the registered holder or beneficial owner would have been entitled to submit a proposal. However, the by-laws of a corporation may include requirements for advance notice to the corporation. A proposal may include nominations for the election of directors if the proposal is signed by one or more holders of shares representing in the aggregate not less than five per cent of the shares or five per cent of the shares of a class or series of shares of the corporation entitled to vote at the meeting to which the proposal is to be presented. This does not preclude nominations made at a meeting of shareholders.
Stockholder Quorum and Vote Requirements	
Under the DGCL, quorum for a stock corporation is a majority of the shares entitled to vote at the meeting unless the certificate of incorporation or bylaws specify a different quorum, but in no event may a quorum be less than one-third of the shares entitled to vote. Unless the DGCL, certificate of incorporation or by-laws provide for a greater vote, generally the required vote under the DGCL is a majority of the shares present in person or represented by proxy, except for the election of directors which requires a plurality of the votes cast.	Unless the by-laws otherwise provide, under the OBCA, the holders of a majority of the shares entitled to vote at the meeting, present in person or represented by proxy, constitute a quorum for a meeting of shareholders. Unless the OBCA, articles of incorporation or a unanimous shareholder agreement provide for a greater number of votes, generally the required votes under the OBCA is a majority of the votes cast by the shareholders who voted in respect of that resolution.

Delaware	Canada
Amendment of Governing Instrument	
Amendment of Certificate of Incorporation. Generally, under the DGCL, the affirmative vote of the holders of a majority of the outstanding stock entitled to vote is required to approve a proposed amendment to the certificate of incorporation, following the adoption of the amendment by the board of directors of the corporation, provided that the certificate of incorporation may provide for a greater vote. Under the DGCL, holders of outstanding shares of a class or series are entitled to vote separately on an amendment to the certificate of incorporation if the amendment would have certain consequences, including changes that adversely affect the rights and preferences of such class or series. *Amendment of By-laws.* Under the DGCL, after a corporation has received any payment for any of its stock, the power to adopt, amend or repeal by-laws shall be vested in the stockholders entitled to vote; provided, however, that any corporation may, in its certificate of incorporation, provide that by laws may be adopted, amended or repealed by the board of directors. The fact that such power has been conferred upon the board of directors shall not divest the stockholders of the power nor limit their power to adopt, amend or repeal the by-laws.	*Amendment to Articles of Incorporation.* Under the OBCA, a corporation may amend its articles to add, change, or remove any provision permitted by the OBCA to be, or that is, set out in its articles. A registered holder or a beneficial owner of shares that are entitled to be voted at an annual meeting of shareholders may also make a proposal to amend the articles. Generally, under the OBCA, an amendment to the articles requires approval by special resolution of the shareholders. A special resolution is a resolution passed by not less than two-thirds of the votes cast by the shareholders who voted in respect of the resolution or signed by all shareholders entitled to vote on that resolution. The holders of the shares of a class or a series (if such series is affected by an amendment in a manner different from other shares of the same class) are entitled to vote separately as a class or series on an amendment to the articles if such amendment would have certain consequences in respect of that such class or series, including increasing or decreasing the number of shares of such class, creating a new class or series equal or superior to such class or series or changing the rights, privileges, restrictions or conditions attached to such class or series. *Amendment to By-Laws.* Under the OBCA, a registered holder or a beneficial owner of shares that are entitled to be voted at a meeting of shareholders may make a proposal to make, amend or repeal a by-law. Unless the articles, by-laws or a unanimous shareholder agreement otherwise provide, the directors may, by resolution, make, amend or repeal any by-laws that regulate the business or affairs of the corporation. The directors shall then submit such by-law, or amendment or repeal of such by-law, to the shareholders at the next meeting of shareholders, and the shareholders may, by ordinary resolution, confirm, reject or amend the by-law, amendment or repeal.
Votes on Mergers, Consolidations and Sales ofAssets	
The DGCL provides that, unless otherwise provided in the certificate of incorporation or by-laws, the adoption of a merger agreement requires the approval of a majority of the outstanding stock of the corporation entitled to vote thereon.	Under the OBCA, the adoption of an amalgamation agreement requires approval by special resolution of the shareholders of each amalgamating corporation by special resolution of the holders of the shares of each class or series entitled to vote thereon. A special resolution is a resolution passed by not less than two-thirds of the votes cast by the shareholders who voted in respect of the resolution or signed by all shareholders entitled to vote on that resolution.
Dissenter's Rights of Appraisal	
Under the DGCL, a stockholder of a Delaware corporation generally has the right to dissent from and request payment for the stockholders shares upon a merger or consolidation in which the Delaware corporation is participating, subject to specified procedural requirements, including that such dissenting stockholder does not vote in favor of the merger or	Under the OBCA, a shareholder may dissent from a transaction and obtain a right of appraisal when the corporation resolves to: a) amend its articles to add, change or remove any provisions restricting or constraining the issue, transfer or ownership of shares of that

consolidation.However, the DGCL does not confer appraisal rights, in certain circumstances, including if the dissenting stockholder owns shares traded on a national securities exchange and will receive publicly traded shares in the merger or consolidation. Under the DGCL, a stockholder asserting appraisal rights does not receive any payment for his or her shares until the court determines the fair value or the parties otherwise agree to a value. The costs of the proceeding may be determined by the court and assessed against the parties as the court deems equitable under the circumstances.	class; b) amend its articles to add, change or remove any restriction on the business or businesses that the corporation may carry on or upon the powers that the corporation may exercise; c) amalgamate with another corporation; d) be continued under the laws of another jurisdiction, the *Co-operative Corporations Act* or the *Not-for-Profit Corporations Act, 2010*; or e) sell, lease or exchange all or substantially all its property. Further, the holders of a class or series of shares entitled to vote as a separate class on an amendment to the articles of incorporation may dissent from such amendment (with certain exceptions, including where the amendments involve certain changes to such class or series where the articles provide that the holders of shares of such class or series are not entitled to dissent). This right to dissent applies even if there is only one class of shares. A shareholder asserting dissent rights is entitled, subject to specified procedural requirements, including sending a written objection to the resolution and providing sufficient notice, when the action approved by the resolution from which the shareholder dissents becomes effective, to be paid by the corporation the fair value of the shares in respect of which the shareholder dissents, determined as of the close of business on the day before the resolution was adopted. A corporation shall not make a payment to a dissenting shareholder if there are reasonable grounds for believing that, (i) the corporation is or, after the payment, would be unable to pay its liabilities as they become due; or (ii) the realizable value of the corporation's assets would thereby be less than the aggregate of its liabilities. Where a corporation fails to make a written offer of payment or a notification that it is unable to lawfully offer payment to the dissenting shareholder, or the dissenting shareholder fails to accept an offer, the corporation or the dissenting shareholder, as the case may be, may apply to a court to fix a fair value for the shares. The court may in its discretion allow a reasonable rate of interest on the amount payable to each dissenting shareholder from the date the action approved by the resolution is effective until the date of payment.

Delaware	Canada
Anti-Takeover and Ownership Provisions	
Unless an issuer opts out of the provisions of Section 203 of the DGCL, Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with a holder of 15% or more of the corporation's voting stock (as defined in Section 203), referred to as an interested stockholder, for a period of three years after the date of the transaction in which the interested stockholder became an interested stockholder, except as otherwise provided in Section 203. For these purposes, the term "business combination" includes mergers, asset sales and other similar transactions with an interested stockholder.	The OBCA contains no restriction on adoption of a shareholder rights plan. The OBCA does not restrict related party transactions; however, in Ontario, takeover bids and related party transactions are addressed in through the provincial securities legislation and policies.
Inspection of Books and Records	
Under the DGCL, any holder of record of stock or a person who is the beneficial owner of shares of such stock held either in a voting trust or by a nominee on behalf of such person may, upon written demand, inspect the corporation's books and records during business hours for a proper purpose and may make copies and extracts therefrom.	Under the OBCA, registered holders of shares, beneficial owners and creditors of a corporation, their agents and legal representatives may examine the records of the corporation, other than a register of individuals with significant control over the corporation, during the usual business hours of the corporation, and may take extracts from those records, free of charge, and, if the corporation is a offering corporation, any other person may do so upon payment of a reasonable fee.

Delaware	Canada
Derivative Actions	
Under the DGCL, a stockholder may bring a derivative action on behalf of a corporation to enforce the corporation's rights if he or she was a stockholder at the time of the transaction which is the subject of the action. Additionally, under Delaware case law, a stockholder must have owned stock in the corporation continuously until and throughout the litigation to maintain a derivative action. Delaware law also requires that, before commencing a derivative action, a stockholder must make a demand on the directors of the corporation to assert the claim, unless such demand would be futile. A stockholder also may commence a class action suit on behalf of himself or herself and other similarly situated stockholders where the requirements for maintaining a class action have been met.	Under the OBCA, a "complainant", which includes a current or former registered holder or beneficial owner of a security of a corporation or any of its affiliates, a current or former director or officer of a corporation or any of its affiliates and any other person who, in the discretion of the court, is a proper person to do so, may make an application to the court to bring an action in the name and on behalf of a corporation or any of its subsidiaries, or intervene in an action to which any such body corporate is a party, for the purpose of prosecuting, defending or discontinuing the action on behalf of the body corporate (a "derivative action"). No derivative action may be brought unless the complainant has given fourteen days' notice to the directors of the corporation or its subsidiary of the complainant's intention to apply to the court to bring a derivative action and the court is satisfied that (i) the directors of the corporation or its subsidiary will not bring, diligently prosecute or defend or discontinue the action; (ii) the complainant is acting in good faith; and (iii) it appears to be in the interests of the corporation or its subsidiary that the action be brought, prosecuted, defended or discontinued. In connection with a derivative action, the court may make any order it thinks fit, including an order requiring the corporation or its subsidiary to pay reasonable legal fees and any other costs reasonably incurred by the complainant in connection with the action

Transfer Agent and Registrar

The transfer agent and registrar for the Company's common shares is Computershare Trust Company of Canada and Computershare Trust Company, N.A. The transfer agent and registrar's address in the United States is 150 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

The Nasdaq Capital Market

The Company's Common Shares are listed on Nasdaq under the symbol "PMN."

Exhibit 10.47

ProMIS Neurosciences (US) Inc.

Larry Alstiel
31 Water Street,
Stonington CT, 06378

BY EMAIL

March 1, 2025

Employment Offer

Dear Larry:

On behalf of ProMIS Neurosciences (US), Inc. (the "**Company**"), I am pleased to offer you employment as Chief Medical Officer ("**CMO**"). The new terms of your employment are set forth below in this Employment Offer (the "**Employment Agreement**").

1. **Position.** Effective as of March 1, 2025 (the "**Effective Date**"), you will serve as the Company's CMO and you will report to the Company's Chief Executive Officer ("**CEO**").

2. **Salary.** The Company will pay you a base salary at the rate of $35,416.67 per month ($425,000 when annualized), payable in accordance with the Company's standard payroll schedule and subject to applicable deductions and withholdings, which shall be retroactive to the Effective Date. Your base salary will be subject to periodic review and adjustments at the Company's discretion. The base salary at any given time shall be referred to as the "Base Salary."

3. **Annual Bonus.** You will be eligible to receive an annual performance bonus targeted at 20% of the Base Salary, as determined by the CEO and Board in their sole discretion. The actual bonus is discretionary and will be subject to the CEO and Board's assessment of your performance as well as business conditions at the Company. In order to receive the bonus payment, you must be employed by the Company on the date such bonus is paid.

4. **Equity**. You were previously granted stock options, which shall remain subject to the ProMIS Neurosciences Inc. Stock Option Plan (the "**Option Plan**") and stock option agreement between you and the Company.

5. **Benefits.** You will be eligible to participate in the employee benefits and insurance programs generally made available to the Company's full-time employees. Details of such benefits programs, including mandatory employee contributions, if any, and waiting periods, if applicable, will be made available to you when such benefit(s) become available.

6. **At-Will Employment; Accrued Obligations.** Your employment will be "at will," meaning you or the Company may terminate it at any time for any or no reason.

Notwithstanding the forgoing and except for termination in the event of your death, any termination of your employment by the Company or by you shall be communicated by written Notice of Termination to the other party hereto. In the event of your resignation without Good

Reason, you agree to provide the Company with at least 30 days' notice which may be waived by the Company in its discretion. In the event of the ending of your employment for any reason, the Company shall pay you (i) your Base Salary as accrued but not paid, through your last day of employment (the "**Date of Termination**"), and (ii) the amount of any documented expenses properly incurred by you on behalf of the Company prior to any such termination and not yet reimbursed (the "**Accrued Obligations**").

7. **Termination Benefits.** In the event the Company terminates your employment for any reason or you resign for any reason, the Company shall pay you the Accrued Obligations. In the event that the Company terminates your employment without Cause (and other than by reason of your death or Disability) or you resign for Good Reason, then provided you enter into, do not revoke and comply with the terms of a separation agreement in a form satisfactory to the Company, which shall include a general release of claims against the Company and related persons and entities (the "**Release**") and such Release becomes irrevocable within the time period set forth in the Release but in no event more than 60 days after the Date of Termination, the Company will provide you with the following "Termination Benefits":

i. a payment that is equivalent to the sum of nine (9) months of your Base Salary (the "**Salary Continuation Payment**"); and

ii. if elected, continuation of group health plan benefits to the extent authorized by and consistent with 29 U.S.C. § 1161 et seq. (commonly known as "**COBRA**"), with the cost of the regular premium for such benefits shared in the same relative proportion by the Company and you as in effect on the Date of Termination until the earlier of (i) twelve (12) months; and (ii) the date you become eligible for health benefits through another employer or otherwise become ineligible for COBRA.

The Salary Continuation shall be paid out in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Salary Continuation Payments shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Employment Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section l.409A-2(b)(2). For the avoidance of doubt, in the event your employment is terminated as a result of death, Disability, or for any reason other than a termination by the Company without Cause or your resignation for Good Reason, you will be entitled to the Accrued Obligations but you will not be entitled to any of the Termination Benefits.

For purposes of this Employment Agreement, the term "**Cause**" means: (i) conduct by you constituting a material act of misconduct in connection with the performance of your duties, including, without limitation, (A) willful repeated failure or refusal to perform material responsibilities that have been requested by the Company; (B) dishonesty to the Company with respect to any material matter; or (C) misappropriation of funds or property of the Company or

any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by you of acts satisfying the elements of (A) any felony or (B) a misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any misconduct by you, regardless of whether or not in the course of your employment, that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries or affiliates if you were to continue to be employed in the same position; (iv) a breach by you of any of the provisions contained in the Employment Agreement or the Restrictive Covenants Agreement, which remains uncured following 30 days' notice from the Company to you; or (v) your material failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

For purposes of this Employment Agreement, "**Disability**" shall mean Disability shall mean you are unable to perform the essential functions of your position under this Employment Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period.

For purposes of this Employment Agreement, "**Good Reason**" means: (i) a material adverse change in your duties and responsibilities; (ii) a material reduction in your Base Salary without your prior consent except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; or (iii) a requirement that you relocate your principal place of employment more than 30 miles. To terminate your employment for Good Reason you must (i) provide notice to the Company of the event giving rise to the Good Reason within 60 days after such event occurs, (ii) provide the Company with at least 30 days to cure (the "Cure Period"), and (iii) if not cured, resign for Good Reason within 30 days following expiration of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

8. **Restrictive Covenants Agreement**. As a condition of your employment, you will be required to execute a Non-Solicitation, Confidentiality and Assignment Agreement in the form attached as Exhibit A (the "**Restrictive Covenants Agreement**"), as a condition of employment.

9. **Third Party Agreements and Rights**. You hereby confirm that you are not bound by the terms of any agreement with any previous employer or other party which restricts your engagement in any business in any way, other than confidentiality restrictions (if any). You represent to the Company that your execution of this Employment Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party.

In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company any copies or other tangible embodiments

of non-public information belonging to or obtained from any such previous employment or other party.

10. **Litigation and Regulatory Cooperation**. During and after your employment, you shall cooperate reasonably with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while you were employed by the Company, (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information and (iii) transitioning your duties. Your reasonable cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your employment, you also shall cooperate reasonably with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. Any reasonable costs incurred by you as part of the foregoing shall be reimbursed by the Company. In addition, you will be compensated (at the Base Salary as applied to a 32-hour week) for your time performing services in accordance with this Section in respect of any period after your employment with the Company ends.

11. **Section 409A.** All in-kind benefits provided and expenses eligible for reimbursement under this Employment Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Employment Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit. The parties intend that this Employment Agreement will be administered in accordance with Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). To the extent that any provision of this Employment Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Employment Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A 2(b)(2). The parties agree that this Employment Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party. The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Employment Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

12. **Withholding; Tax Effect.** All forms of compensation referred to in this

Employment Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or the Board related to tax liabilities arising from your compensation.

13. **Entire Agreement.** This Employment Agreement, together with the Restrictive Covenants Agreement, constitutes the complete agreement between you and the Company, contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company.

14. **Governing Law; Jurisdiction.** This Employment Agreement will be governed by the laws of the Commonwealth of Massachusetts, excluding laws relating to conflicts or choice of law. You and the Company each submit to the exclusive personal jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts with respect to any dispute, controversy or claim arising out of or in connection with this Agreement, including the validity, invalidity, breach or termination thereof, and including tort claims.

15. **Assignment; Successors and Assigns.** Neither you nor the Company may make any assignment of this Employment Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Employment Agreement without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further that (without limiting the provisions of Section 7 of this Employment Agreement) if you remain employed or become employed by the Company, the purchaser or any of their affiliates in connection with any such transaction, then you shall not be entitled to any payments or benefits pursuant to Section 7 of this Employment Agreement solely as a result of such transaction. This Employment Agreement shall inure to the benefit of and be binding upon you and the Company, and each of your and the Company's respective successors, executors, administrators, heirs and permitted assigns.

16. **Waiver; Amendment.** No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Employment Agreement, or the waiver by any party of any breach of this Employment Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized representative of the Company.

17. **Enforceability.** If any portion or provision of this Employment Agreement (including, without limitation, any portion or provision of any section of this Employment Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Employment Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or

unenforceable, shall not be affected thereby, and each portion and provision of this Employment Agreement shall be valid and enforceable to the fullest extent permitted by law.

18. **Other Terms.** The provisions of this Employment Agreement shall survive the termination of your employment to the extent necessary to effectuate the terms contained herein. The headings and other captions in this Employment Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Employment Agreement. This Employment Agreement may be executed in separate counterparts. When both counterparts are signed, they shall be treated together as one and the same document. PDF copies of signed counterparts shall be equally effective as originals.

[SIGNATURE PAGE FOLLOWS]

To accept the terms of this Employment Agreement, please sign it and return it to the Company.

Very truly yours,

s/ Neil K. Warma

Name: Neil Warma
Title: Chief Executive Officer

I have read and accept this employment offer:

s/ Larry Altstiel

Name: Larry Altstiel, M.D., Ph.D

Certain identified information has been excluded from the exhibit pursuant to Item 601(a)(6) of Regulation S-K or pursuant to Item 601(b)(10)(iv) because it is both not material and is the type of information that the registrant treats as private or confidential. Redacted information is indicated by: [***]

Exhibit 10.75

THE UNIVERSITY OF BRITISH COLUMBIA

February 12, 2026 UBC File: F16-05805 / 2026-2011

VIA EMAIL

Neil K. Warma
President and CEO
ProMIS Neurosciences, Inc.
Suite 200, 1920 Yonge Street
Toronto, ON M4S 3E2

Re: Collaborative Research Agreement between The University of British Columbia and Vancouver Coastal Health Authority (collectively the "Institution") and ProMIS Neurosciences, Inc. (the "Sponsor"), effective as of April 1, 2016 and amended on December 13, 2017, July 5, 2018, February 13, 2019, September 9th, 2019, January 11, 2022 and December 2, 2024 (the "Agreement"); Amendment No. 7

The Institution and Sponsor have executed the Agreement and hereby agree to amend the Agreement as follows:

Any reference in the Agreement to Schedule "A" shall be understood to also include a reference to Schedule "A-2" as attached to this Amendment No. 7.

The first two paragraphs of Article 4.1 will be replaced with the following:

4.1 The Parties understand and agree that, subject to Article 4.3 and excluding any intellectual property related costs under Section 7, the total costs to the Sponsor hereunder will be CAD $6,630,000. The Parties acknowledge that any budget categories that may be described in the Project are estimates only and that changes from category to category may be made at the Institution's discretion.

As of February 9, 2026, the Sponsor has already paid an amount of CAD $5,630,000. The Sponsor will pay the remaining amount of CAD $1,000,000 in five equal installments, each within 30 days of receipt of an invoice (to be) sent in accordance with the following invoicing schedule:

i.	January 15, 2026	$200,000
ii.	March 1, 2026	$200,000
iii.	June 1, 2026	$200,000
iv.	September 1, 2026	$200,000
v.	December 1, 2026	$200,000

Each invoice will contain the required payment details.

Certain identified information has been excluded from the exhibit pursuant to Item 601(a)(6) of Regulation S-K or pursuant to Item 601(b)(10)(iv) because it is both not material and is the type of information that the registrant treats as private or confidential. Redacted information is indicated by: [***]

Articles 16.0 (Notices) will be deleted in its entirety and replaced with the following:

16.1 All legal notices will be sent electronically using the email address below, or to such other address that a Party may designate. A notice will be deemed delivered at the time of successful transmission.

a. Institution: [***], with a copy to [***]
b. Company: [***]

All other terms and conditions of the Agreement will remain in full force and effect and will continue for the duration of the Agreement. The Agreement and this Amendment No. 7 will be read together and constitute one agreement.

This Amendment to the Agreement may be signed in counterparts either through original copies or electronically each of which will be deemed an original and all of which will constitute the same instrument.

Signed for and on behalf of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatory:

/s/ John-Paul Heale
Name: Dr. John-Paul Heale
Title: Managing Director, UILO
Date: 2/17/2026

Signed for and on behalf of
PROMIS NEUROSCIENCES, INC.
by its authorized signatory:

/s/ Neil Warma
Name: Neil Warma
Title: CEO
Date: 2/12/2026

Signed for and on behalf of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatory:

/s/ Jennifer Lynett
Name: Jennifer Lynett
Title: Associate Director Sponsored Research
Date: 2/13/2026

Signed for and on behalf of
VANCOUVER COASTAL HEALTH AUTHORITY
by its authorized signatory:

/s/ James Johnson
Name: Dr. James Johnson
Title: Professor, Faculty of Medicine, UBC
Date: 2/17/2026

Acknowledged by

/s/ Neil Cashman
Dr. Neil Cashman
Principal Investigator
Date:

Certain identified information has been excluded from the exhibit pursuant to Item 601(a)(6) of Regulation S-K or pursuant to Item 601(b)(10)(iv) because it is both not material and is the type of information that the registrant treats as private or confidential. Redacted information is indicated by: [***]

SCHEDULE "A-2"

[***]

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Company Name	Jurisdiction
ProMIS Neurosciences (US), Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-274656, 333-274658, 333-281841, 333-289577, 333-290039 and 333-294408), Post-Effective Amendment on Form S-3 to Registration Statement on Form S-1 (File No. 333-268103) and Form S-8 (File No. 333-267319 and 333-289579) of our report dated March 25, 2026, relating to the consolidated financial statements of ProMIS Neurosciences Inc., appearing in this Annual Report on Form 10-K.

/s/ BAKER TILLY US, LLP

Tewksbury, Massachusetts
March 25, 2026

Exhibit 31.1

CERTIFICATIONS

I, Neil Warma, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of ProMIS Neurosciences Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2026

/s/ Neil Warma

Neil Warma
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Daniel Geffken, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of ProMIS Neurosciences Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2026

/s/ Daniel Geffken

Daniel Geffken
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

STATEMENT PURSUANT TO
18 U.S.C. SECTION 1350
AS REQUIRED BY
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ProMIS Neurosciences Inc. (the "Company") on Form 10-K for the period ending December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 25, 2026	/s/ Neil Warma Neil Warma	Chief Executive Officer (Principal Executive Officer)
March 25, 2026	/s/ Daniel Geffken Daniel Geffken	Chief Financial Officer (Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to ProMIS Neurosciences Inc. and will be retained by ProMIS Neurosciences Inc. and furnished to the Securities and Exchange Commission or its staff upon request.