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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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 001-40360

Mind Medicine (MindMed) Inc.

(Exact name of Registrant as specified in its Charter)

British Columbia, Canada	**98-1582438**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One World Trade Center, Suite 8500 New York, New York	**10007**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (212) 220-6633

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	**MNMD**	**The Nasdaq Stock Market LLC** (The Nasdaq Global Select 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 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, 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 § 240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 28, 2024, the aggregate market value of the Registrant's common shares held by non-affiliates of the Registrant was $515.4 million based on the closing price of the Registrant's common shares, as reported by the Nasdaq Stock Market, on such date.

The number of the Registrant's common shares outstanding as of February 20, 2025 was 75,368,359.

DOCUMENTS INCORPORATED BY REFERENCE

The following materials are incorporated by reference into this Form 10-K:

Part III of this report incorporates information by reference from the Company's definitive proxy statement, which proxy statement is due to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2024.

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Unless otherwise noted or the context indicates otherwise, references in this Annual Report on Form 10-K (this "Annual Report") to the "Company," "MindMed," "we," "us," and "our" refer to Mind Medicine (MindMed) Inc. and its consolidated subsidiaries.

This report contains references to our trademarks and trade names and to trademarks and trade names belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks or trade names to imply a relationship with, or endorsement or sponsorship of us or our business by, any other companies.

All currency amounts in this Annual Report are stated in United States dollars, which is our reporting currency, unless otherwise noted. All references to "dollars" or "$" are to United States dollars and all references to "CAD$" are to Canadian dollars.

Special Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would" or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the timing, progress and results of our investigational programs for MM120, a proprietary, pharmaceutically optimized form of lysergide D-tartrate (LSD), MM402, also referred to as R(-)-MDMA (together, our "lead product candidates") and any other product candidates (together with our lead product candidates, our "product candidates");
- our reliance on the success of our investigational MM120 product candidate;
- our expectations regarding our cash runway;
- the protocols and timing of availability of data from our ongoing Phase 3 clinical program for MM120 orally disintegrating tablet ("ODT") in generalized anxiety disorder ("GAD");
- the protocol, timing of the initiation and availability of data from our Phase 3 clinical program for MM120 in major depressive disorder ("MDD");
- the timing, scope or likelihood of regulatory filings and approvals and our ability to obtain and maintain regulatory approvals for product candidates for any indication;
- our expectations regarding the size of the eligible patient populations for our lead product candidates, if approved and commercialized;
- our ability to identify third-party treatment sites to conduct our trials and our ability to identify and train appropriate qualified healthcare practitioners ("HCPs") to administer our treatments;
- our ability to implement our business model and our strategic plans for our product candidates;
- our ability to identify new indications for our lead product candidates beyond our current primary focuses;
- our ability to achieve profitability and then sustain such profitability;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing, coverage and reimbursement of our lead product candidates, if approved and commercialized;
- the rate and degree of market acceptance and clinical utility of our lead product candidates, in particular, and controlled substances, in general;
- future investments in our business, our anticipated capital expenditures and our estimates regarding our capital requirements;
- our ability to establish or maintain collaborations or strategic relationships or to obtain additional funding;
- our expectations regarding potential benefits of our lead product candidates;
- our ability to maintain effective patent rights and other intellectual property protection for our product candidates, and to prevent competitors from using technologies we consider important in our successful development and commercialization of our product candidates;
- infringement or alleged infringement on the intellectual property rights of third parties;

- legislative and regulatory developments in the United States, including individual states, the UK, the European Union and other jurisdictions, including decisions by the U.S. Drug Enforcement Administration ("DEA") and states to reschedule any of our product candidates, if approved, containing Schedule I controlled substances, before they may be legally marketed in the U.S.;

- the effectiveness of our internal control over financial reporting;

- actions of activist shareholders against us that have previously been and could be disruptive and costly and may result in litigation and have an adverse effect on our business and stock price;

- the impact of adverse global economic conditions, including public health crises, geopolitical conflicts, fluctuations in interest rates, supply-chain disruptions and inflation, on our financial condition and operations;

- our Loan Agreement (as defined herein) contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation;

- our expectations regarding our revenue, expenses and other operating results;

- the costs and success of our marketing efforts, and our ability to promote our brand;

- our reliance on key personnel and our ability to identify, recruit and retain skilled personnel;

- our ability to effectively manage our growth; and

- our ability to compete effectively with existing competitors and new market entrants.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. Management's beliefs and assumptions, including the non-occurrence of the risks and uncertainties described in this Annual Report or other significant events occurring outside of our normal course of business, are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements may turn out to be inaccurate. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. And while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Annual Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

We may announce material business and financial information to our investors using our investor relations website (https://ir.mindmed.co/). We therefore encourage investors and others interested in our company to review the information that we make available on our website, in addition to following our filings with the Securities and Exchange Commission, webcasts, press releases and conference calls. Our website and information included in or linked to our website are not part of this Annual Report.

Summary of Selected Risk Factors

The following is a summary of the principal risks associated with an investment in our common shares:

- We have a limited operating history, have not completed any pivotal clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

- We are a clinical-stage pharmaceutical company and have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

- We have never generated revenue and may never be profitable.

- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

- We are dependent on the successful development of our product candidates. We cannot give any assurance that any of our product candidates will successfully complete clinical trials or receive regulatory approval, which is necessary before a product candidate can be commercialized.

- Drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals, which would mean that we would be unable to commercialize our product candidates on a timely basis or at all, which will adversely affect our business.

- Our focus is on product candidates that are subject to controlled substance laws and regulations in the territories where the products are being developed and will be marketed, if approved, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations and our financial condition, both during clinical development and post approval, if any. In addition, the FDA and/or other regulatory bodies may require additional data, including with respect to abuse potential of our product candidates, before allowing us to commence a clinical trial or before approving any future marketing application we may submit.

- Our product candidates are controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding controlled substances and psychedelics may negatively influence the success of our product candidates.

- We may not achieve our publicly announced milestones according to schedule, or at all.

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

- We face competition from other biotechnology and pharmaceutical companies and our financial condition and operations will suffer if we fail to effectively compete.

- If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

- We rely, and expect to continue to rely, on third parties, including independent clinical investigators, academic collaborators and contract research organizations ("CROs"), to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- Our business and operations could be negatively affected if we become subject to any securities litigation or shareholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

PART I

Item 1. Business.

Overview

We are a late-stage clinical biopharmaceutical company developing novel product candidates to treat brain health disorders. Our mission is to be the global leader in the development and delivery of treatments for brain health disorders that unlock new opportunities to improve patient outcomes. We are developing a pipeline of innovative product candidates targeting neurotransmitter pathways that play key roles in brain health disorders. This specifically includes pharmaceutically optimized product candidates derived from the psychedelic and empathogen drug classes including MM120 and MM402, our lead product candidates.

Our lead product candidate, MM120, is a proprietary, pharmaceutically optimized form of lysergide D-tartrate that we are developing for the treatment of generalized anxiety disorder and major depressive disorder. In December 2023, we announced positive topline results from our Phase 2b clinical trial of MM120 for the treatment of GAD. The trial met its primary endpoint, with MM120 demonstrating statistically significant and clinically meaningful dose-dependent improvements on the Hamilton Anxiety Rating Scale ("HAM-A") compared to placebo at Week 4. In March 2024, we announced that the U.S. Food and Drug Administration ("FDA") granted breakthrough designation to our MM120 program for the treatment of GAD. We also announced in March 2024 that our Phase 2b clinical trial of MM120 in GAD met its key secondary endpoint, and 12-week topline data demonstrated clinically and statistically significant durability of activity observed through Week 12.

On June 20, 2024, we announced the completion of our End-of-Phase 2 meeting with the FDA, supporting the advancement of MM120 into pivotal trials for the treatment of adults with GAD. Our Phase 3 clinical program for MM120 orally disintegrating tablet is expected to consist of two clinical trials: the Voyage study (MM120-300) and the Panorama study (MM120-301). Both trials are comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel-group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Voyage is anticipated to enroll approximately 200 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo) and Panorama is anticipated to enroll approximately 250 participants (randomized 2:1:2 to receive MM120 ODT 100 µg, MM120 ODT 50 µg or placebo). We expect both trials will utilize an adaptive trial design with a blinded interim sample size re-estimation, allowing for an increase in sample size by up to 50% in each trial in the case of certain parameters. The primary endpoint for each trial is the change from baseline in HAM-A score at Week 12 between MM120 ODT 100 µg and placebo. On December 16, 2024, we announced the initiation of Voyage, with an anticipated topline readout (Part A results) in the first half of 2026. On January 30, 2025, we announced the initiation of Panorama, with an anticipated topline readout (Part A results) in the second half of 2026. Both trials are subject to ongoing regulatory review and discussions, which could result in changes to trial design, including of the Phase 3 clinical trials.

In addition to our Phase 3 clinical program for GAD, we are developing MM120 ODT for the treatment of MDD. In the first quarter of 2024, we held a pre-IND meeting with FDA to discuss the initiation of our Phase 3 clinical program for MM120 ODT in MDD and the trial design for our planned Emerge study (MM120-310), which like our pivotal trials in GAD, we anticipate will be comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Emerge is anticipated to enroll at least 140 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo). The primary endpoint is the change from baseline in Montgomery Åsberg Depression Rating Scale ("MADRS") score at Week 6 between MM120 ODT 100 µg and placebo. We expect to initiate Emerge in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026. We expect to conduct a second Phase 3 pivotal trial in MDD, with the trial design and timing to be informed by the progress from Emerge and additional regulatory discussions.

Our second lead product candidate, MM402, also referred to as R(-)-MDMA, is our proprietary form of the R-enantiomer of 3,4-methylenedioxymethamphetamine (“MDMA”), which we are developing for the treatment of autism spectrum disorder (“ASD”). MDMA is a synthetic molecule that is often referred to as an empathogen because it is reported to increase feelings of connectedness and compassion. Preclinical studies of R(-)-MDMA demonstrated its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggests that it has the potential to exhibit less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer. In October 2024, we completed our first clinical trial of MM402, a single-ascending dose trial in adult healthy volunteers. The data from this Phase 1 clinical trial helped to characterize the tolerability,

pharmacokinetics and pharmacodynamics of MM402. We expect to initiate further trials of MM402 for the treatment of ASD, with the exact timing and scope of such trials to be determined.

Beyond our clinical stage product candidates, we are exploring additional programs, including through external collaborations, which we seek to expand our drug development pipeline and broaden the potential applications of our lead product candidates. These research and development programs include non-clinical, pre-clinical and human clinical trials of current and new product candidates and research compounds with our collaborators.

Our business is premised on a growing body of research supporting the use of novel psychoactive compounds to treat a myriad of brain health disorders. For all product candidates, we intend to proceed through research and development, and with marketing of the product candidates that may ultimately be approved pursuant to the regulations of the FDA and the regulations in other jurisdictions. This entails, among other things, conducting clinical trials with research scientists, using internal and external clinical drug development teams, producing and supplying product candidates according to current Good Manufacturing Practices ("cGMP"), and conducting all trials and development in accordance with the regulations of the FDA, and other regulations in other jurisdictions.

We were incorporated under the laws of the Province of British Columbia in 2010. Our wholly-owned subsidiary, Mind Medicine, Inc. ("MindMed US"), was incorporated in Delaware in 2019. Prior to February 27, 2020, our operations were conducted through MindMed US.

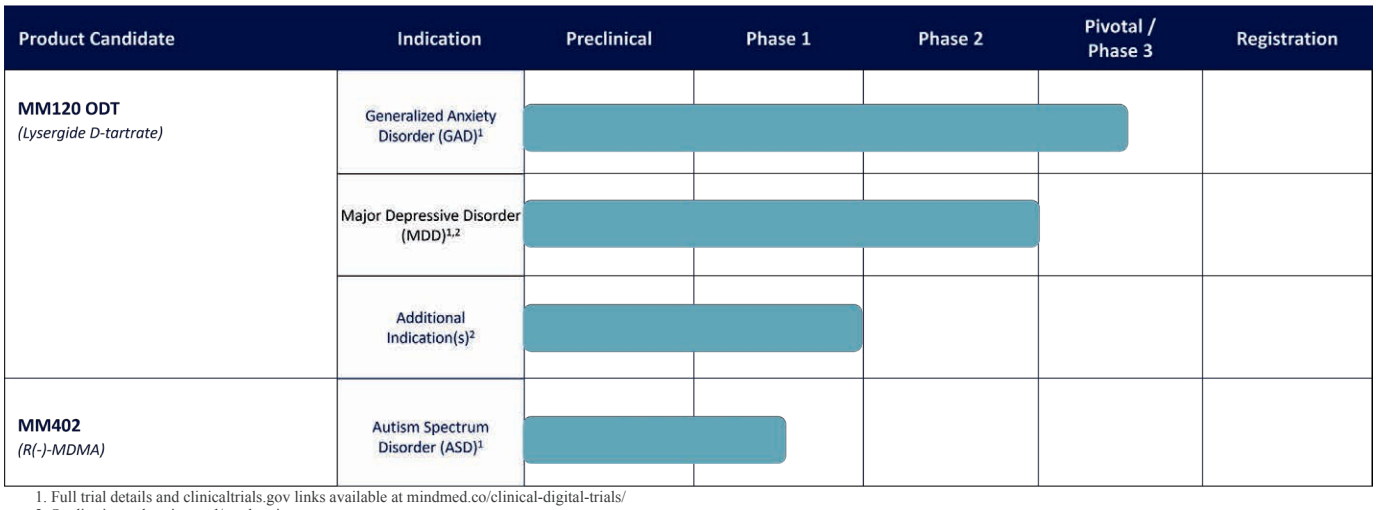
Our Strategy

Our mission is to be the global leader in the development and delivery of treatments for brain health disorders that unlock new opportunities to improve patient outcomes. We intend to accomplish our mission by leading in psychedelic research and development, commercialization and patient access, with a focus on completing our Phase 3 clinical trials of MM120 ODT in GAD and MDD. Key elements of our strategy are to:

- advance our clinical pipeline and submit new drug applications ("NDAs") to the FDA, and conduct pre-launch activities with respect to any of our product candidates that have been successfully developed;
- commercialize any product candidates for which we obtain regulatory approval, including securing the manufacture of commercial supplies;
- continue our research and development efforts to evaluate the potential for our product candidates to treat additional indications, including by exploring new formulations or new delivery methods;
- identify new targets, and generate and test new compounds and product candidates, with a focus on indications where we believe we can make well-informed, rapid go/no-go decisions, with the goal of developing a diversified portfolio of product candidates with differentiated features;
- evaluate the market potential and regulatory pathways for our product candidates in the United Kingdom (the "UK"), European Union (the "EU"), and other countries or regions outside the United States, and determine the best strategic and business opportunities to advance our product candidates in these markets;
- continue to build, maintain, defend, leverage and expand our intellectual property portfolio, including by utilizing the strengths of our scientific know-how to expand our portfolio of new chemical entities to lessen our long-term reliance on the success of any one program and to facilitate long-term growth; and
- continue to explore opportunities to establish agreements or alliances with other pharmaceutical companies, at the appropriate time, where we believe a collaboration or other commercial agreement will add significant value to our efforts, including through capabilities, infrastructure, speed or financial contributions, or to acquire new compounds, product candidates or products if we believe such opportunities will help us achieve our goals or meet other strategic objectives.

Our Product Candidate Pipeline

The following table summarizes the status of our portfolio of product candidates:



1. Full trial details and clinicaltrials.gov links available at mindmed.co/clinical-digital-trials/
2. Studies in exploration and/or planning stage.
R(-)-MDMA: rectus-3,4-methylenedioxymethamphetamine

MM120 (Lysergide D-tartrate)

MM120, or lysergide D-tartrate, is our proprietary product candidate, a pharmaceutically optimized form of lysergide D-tartrate being developed for GAD, MDD and other brain health disorders. Lysergide was first synthesized in 1938 and its psychoactive properties were discovered in 1943. From 1949 to 1966, lysergide was used by psychiatrists and researchers to gain insights into the world of brain health and to assist psychotherapy. The precise mechanism by which lysergide modulates anxiety and depression is still under investigation, but recent neuroimaging studies have provided a plausible explanation for clinical efficacy in these disease areas. Lysergide decreases the functional integrity of brain networks and the separation between networks while also enhancing neurogeneration. At the whole-brain level, lysergide increases functional connectivity between various brain regions and increases measures of functional 'brain entropy' across many functional systems. This increase in connectivity between brain regions is correlated with ego dissolution and other aspects of the lysergide experience that are believed to contribute to subsequent and persistent improvements in psychological functioning. Acute and persistent reconfiguration of brain networks by lysergide—particularly prefrontal and default mode network regions— may represent systems-level mechanisms underlying its therapeutic effects in anxiety, depression and other brain health disorders. Lysergide has been investigated for its applications in the treatment of anxiety associated with terminal cancer, depression, alcohol use disorder, and opioid use disorder, among other conditions.

General Anxiety Disorder (GAD)

GAD is a chronic, often debilitating mental health disorder that affects approximately 10% of U.S. adults in their lifetimes. Symptoms of GAD include excessive anxiety and worry that persists for over six months, which can lead to significant impairments in social, occupational and other functioning, according to the National Institute of Mental Health. While there is substantial diagnostic overlap between GAD, MDD, and other major brain health disorders, there has been very little innovation focused on the treatment of GAD in the past several decades due to the shift in focus from anxiety disorders, like GAD, toward depressive disorders, like MDD.

In December 2023, we announced positive topline results from our Phase 2b clinical trial of MM120 for the treatment of GAD. The trial met its primary endpoint, with MM120 demonstrating statistically significant and clinically meaningful dose-dependent improvements on the HAM-A scale compared to placebo at Week 4. MM120 was administered as a single-dose in a monitored clinical setting with no additional therapeutic intervention. MM120 100 µg - the dose achieving the highest level of clinical activity - demonstrated a 7.6-point reduction compared to placebo at Week 4 (-21.3 MM120 vs. -13.7 placebo; $p<0.0004$; Cohen's $d=0.88$). Clinical Global Impressions-Severity ("CGI-S") scores on average improved from 4.8 to 2.4 in the 100 ug dose group, representing a two-category shift from 'markedly ill' to 'borderline ill' at Week 4 ($p<0.001$). This clinical activity was observed to be rapid and durable beginning on Day 2 and continuing through Week 4 with no loss.

In March 2024, we announced that the FDA granted breakthrough designation to our MM120 program for the treatment of GAD. We also announced in March 2024 that our Phase 2b trial of MM120 in GAD met its key secondary endpoint, and 12-week topline data demonstrated clinically and statistically significant durability of activity observed through Week 12. MM120 100µg—the dose with

optimal clinical activity observed in the trial—demonstrated a 7.7-point improvement over placebo at Week 12 (-21.9 MM120 vs. -14.2 placebo; p<0.003 Cohen's d=0.81), with a 65% clinical response rate and a 48% clinical remission rate sustained to Week 12. Clinical Global Impressions -Severity (CGI-S) scores on average improved from 4.8 to 2.2 in the 100µg dose group, representing a two-category shift from 'markedly ill' to 'borderline ill' at Week 12 (p<0.004). This clinical activity was rapid, observed as early as trial day 2, and durable with further improvements observed in mean HAM-A or CGI-S scores between Weeks 4 and 12.

In the Phase 2b trial, MM120 was generally well-tolerated with most adverse events mild to moderate, transient and primarily occurring on dosing day, consistent with expected acute effects of the study drug. The most common adverse events, with at least 10% incidence on dosing day in the 100 µg dose group, included illusion, nausea, headache, hallucination, euphoric mood, anxiety, mydriasis, hyperhidrosis, paresthesia, fatigue, blood pressure increase, abnormal thinking, and altered state of consciousness.

Prior to treatment with MM120, trial participants were clinically tapered and then washed out from any anxiolytic or antidepressant treatments and did not receive any form of study-related psychotherapy for the duration of their participation in the trial.

On June 20, 2024, we announced the completion of our End-of-Phase 2 meeting with the FDA, supporting the advancement of MM120 ODT into pivotal trials for the treatment of adults with GAD. Our Phase 3 clinical program for MM120 ODT is expected to consist of two clinical trials: the Voyage study (MM120-300) and the Panorama study (MM120-301). Both trials are comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel-group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Voyage is anticipated to enroll approximately 200 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo) and Panorama is anticipated to enroll approximately 250 participants (randomized 2:1:2 to receive MM120 ODT 100 µg, MM120 ODT 50 µg or placebo). We expect both trials will utilize an adaptive trial design with a blinded interim sample size re-estimation, allowing for an increase in sample size by up to 50% in each trial in the case of certain parameters. The primary endpoint for each trial is the change from baseline in HAM-A score at Week 12 between MM120 ODT 100 µg and placebo. On December 16, 2024, we announced the initiation of Voyage, with an anticipated topline readout (Part A results) in the first half of 2026. On January 30, 2025, we announced the initiation of Panorama with an anticipated topline readout (Part A results) in the second half of 2026. Both trials are subject to ongoing regulatory review and discussions, which could result in changes to trial design, including of the Phase 3 clinical trials.

On December 5, 2024, we announced that MM120 ODT has been granted an Innovation Passport designation for the treatment of GAD under Innovative Licensing and Access Pathway ("ILAP") by the UK. Medicines and Healthcare products Regulatory Agency ("MHRA"). The Innovation Passport is the entry point to the ILAP, which aims to accelerate time to market and facilitate patient access to medicines in the UK.

Major Depressive Disorder (MDD)

In 2023, it is estimated that 21.9 million adults in the U.S. experienced at least one major depressive episode ("MDE"). MDD is characterized by the presentation of five or more depressive symptoms, occurring for at least 2 weeks, and is the second most common mental health disorder in the U.S. Symptoms of MDD may include feelings of worthlessness, fatigue, impaired social functioning and recurrent thoughts of death. MDD is associated with significant morbidity and mortality, serious functional impairment, and reduced quality of life. MDD also leads to substantial economic burdens due to higher direct and indirect costs. For patients who experience an MDE, fewer than half will receive adequate or any pharmacotherapy. Among those treated, approximately 2/3 will not achieve remission from 1st line therapy.

We are also developing MM120 ODT for the treatment of MDD. In the first quarter of 2024, we held a pre-IND meeting with FDA to discuss the initiation of our Phase 3 clinical program for MM120 ODT in MDD and the trial design for our planned Emerge study (MM120-310), which like our pivotal trials in GAD, we anticipate will be comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Emerge is anticipated to enroll at least 140 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo). The primary endpoint is the change from baseline in MADRS score at Week 6 between MM120 ODT 100 µg and placebo. We expect to initiate Emerge in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026. We expect to conduct a second Phase 3 registrational trial in MDD, with the trial design and timing to be informed by the progress from Emerge and additional regulatory discussions.

Given the highly comorbid nature of MDD and GAD, it is common to assess the impact on both depression and anxiety symptoms in clinical trials of either population. As such, in our Phase 2b GAD trial, one of the secondary endpoints was the change from baseline in depression symptoms (as measured by the MADRS score) at week 6 between MM120 and placebo. In March of 2024, we announced

that MM120 100 µg demonstrated statistically and clinically significant reductions in comorbid depressive symptoms, with a MADRS score improvement of 18.7 points on compared to placebo.

MM402 (R(-)-MDMA)

MM402, or R(-)-MDMA, is our proprietary form of the R-enantiomer of MDMA, which we are developing for the treatment of ASD. MDMA is a synthetic molecule that is often referred to as an empathogen because it is reported to increase feelings of connectedness and compassion. R(-)-MDMA is thought to increase the levels of serotonin and, to a lesser extent, norepinephrine, and dopamine, in the brain, resulting in feelings of increased sociability and interpersonal emotional warmth. Preclinical studies of R(-)-MDMA demonstrate its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggest that it could exhibit better tolerability compared to racemic MDMA or the S(+)-enantiomer. In October 2024, we completed our first clinical trial of MM402, a single-ascending dose trial in adult healthy volunteers. The data from this Phase 1 clinical trial helped to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM402. We expect to initiate further trials of MM402 for the treatment of ASD, with the exact timing and scope of such trials to be determined.

ASD is a biologically based neurodevelopmental disorder characterized by persistent deficits in social communication and social interaction, and restricted, repetitive patterns of behavior, interests, and activities. Estimates of the prevalence of ASD vary with study methodology and the population that is evaluated. The overall prevalence of ASD in Europe, Asia, and the United States ranges from 2 to 25 per 1000, or approximately 1 in 40 to 1 in 500. The pathogenesis of ASD is incompletely understood. The general consensus is that ASD is caused by genetic factors that alter brain development resulting in the neurobehavioral phenotype. Environmental and perinatal factors account for few cases of ASD but may modulate underlying genetic factors. Existing psychopharmacologic agents do not target the core symptoms of ASD and are largely oriented around treating coexisting psychiatric illnesses and reducing behavioral dysregulation.

Further Exploration of Novel Biopharmaceuticals and Other Areas of Interest

Beyond our lead product candidates, we have several additional programs, including through external collaborations, through which we seek to expand our drug development pipeline and broaden the potential application of our lead product candidates. These research programs include non-clinical, pre-clinical and human clinical trials of current and new product candidates and research compounds with our collaborators.

Manufacturing & Supply

MM120 and MM402 are small molecules isolated as stable crystalline solids. We believe the syntheses of these product candidates are reliable and reproducible from readily available starting materials, and the synthetic routes are amenable to large-scale manufacturing. We expect to continue to identify and develop product candidates that are amenable to cost-effective manufacturing at the facilities of many third-party contract development and manufacturing organizations ("CDMOs"). Whenever possible, we seek to develop proprietary forms of active pharmaceutical ingredients and/or novel formulations which could provide enhancements in the pharmaceutical profile of our product candidates, including for instance improvements in the stability, manufacturability, pharmacokinetics and/or pharmacodynamics profile of our product candidates.

We neither own nor operate, and currently have no plans to own or operate, any manufacturing facilities. We currently develop and source all of our clinical and non-clinical drug substance and drug product supply through several CDMOs on a purchase order basis under master service and quality agreements. We have also developed and sourced the proprietary formulations of our product candidates from CDMOs, and intend to source all of our future clinical supplies of our product candidates from CDMOs that comply with applicable cGMP.

While we seek to enhance our market protection strategy by identifying unique and/or proprietary methods of manufacturing and/or dosage forms and entering into exclusive long-term or commercial supply agreements, we do not currently have arrangements in place for either commercial supply or redundant supply of drug substance or drug product for our research compounds and product candidates. We intend to enter into a long-term supply agreement at the appropriate time for drug substance and drug product for each product candidate, as and if clinical development of our product candidates continues. We plan to mitigate potential commercial supply risks for any products that are approved in the future through inventory management and through exploring additional manufacturers to provide drug substance or drug product.

Through our third-party manufacturers, we have or intend to refine and scale up the manufacturing process for our product candidates and manufacture clinical supplies as our development program progresses. We believe we currently have sufficient drug

substance for our ongoing trials and believe we will have access and steady supply of drug substance for our planned and future clinical trials.

Catalent

In August 2023, we announced an exclusive licensing agreement with Catalent for its patented Zydis® ODT technology. Under the terms of the licensing agreement, Catalent has granted us access to its Zydis technology for the development of MM120. The agreement also provides us with exclusive rights for the use of the Zydis technology to develop all salt and polymorphic forms of lysergide in the United States, United Kingdom, and European Union among other key jurisdictions. Zydis ODT is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water. Zydis is also recognized as one of the world's best performing ODTs and has well-established advantages over conventional oral dosage forms, including improved patient compliance, adherence and convenience.

UHB Research and Development Collaborations

On April 1, 2020, we entered into a multi-year, exclusive collaboration with Dr. Matthias Liechti's lab at UHB (the "UHB Liechti Lab"), a leading pharmacology and clinical research group studying psychedelic substances based in Basel, Switzerland. Pursuant to the agreement, we acquired exclusive worldwide rights to data, compounds, and patent rights associated with the UHB Liechti Lab's research with lysergide and other psychedelic compounds, including data from preclinical studies and completed or ongoing clinical trials of lysergide and MDMA.

Pursuant to our agreement, we may support certain research programs, as well as certain clinical trials under the direction of Dr. Liechti. Dr. Liechti, as principal investigator, has primary responsibility for such research trials of the selected compounds. Subject to certain terms and conditions, we provide research funding and certain milestone payments in return for the exclusive license to existing and future data and intellectual property generated from clinical trials. Subject to terms and conditions, the UHB Liechti Lab may receive royalties and development revenue on any commercially marketed products developed through the collaboration.

Intellectual Property

We strive to protect the proprietary know-how and technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and compositions, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business. We may also rely on trademarks and/or trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. To protect our rights to our proprietary know-how and technology, we require all employees, as well as our consultants and CROs, when feasible, to enter into agreements that generally require disclosure and assignment to us of ideas, developments, discoveries and inventions made by these employees, consultants, and contract research organizations ("CROs") in the course of their service to us. On occasion, we also enter into research and development agreements with CDMOs in which certain intellectual property is shared jointly with CDMOs.

We plan to continue to expand our intellectual property estate by filing patent applications directed to compositions, methods of use, treatment and patient selection, formulations and manufacturing processes created or identified from our ongoing development of our product candidates. Our success depends in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our proprietary rights from others infringing our proprietary rights; preserve the confidentiality of our trade secrets; and operate without infringing the valid and enforceable patents and proprietary rights of third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We may also rely on trademarks, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We seek to obtain U.S. and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing, or may in the future pursue, will issue as patents in any particular jurisdiction or whether the claims of any issued patents will be enforceable or provide sufficient protection from competitors.

Patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, or not at all, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO") or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Our patent portfolio, as of March 1, 2025, contains ten issued U.S. patents, 49 pending U.S. applications, and 8 pending patent cooperation treaty applications that are either solely owned by us or in-licensed, as well as certain foreign counterparts of a subset of these patent applications in foreign countries, including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Singapore, South Korea, and Taiwan. For lysergide, these patents and patent applications are directed to methods of treatment, analytical methods, compositions of matter, and formulations. For MDMA, these patent applications are directed to R(-)-MDMA and prodrugs thereof, including methods of treatment, methods of manufacture, and compositions of matter. If issued, the 20-year term expiration dates from which our patents will expire is between 2041 to 2044, not including any extension of the patent term that may be available in certain jurisdictions. We continue to seek to maximize the scope of our patent protection for all our programs.

In addition to patents, we also rely upon trademarks, trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We have U.S. trademark registrations for MINDMED and our brain logo in the U.S., as well as pending trademark applications for MINDMED and our brain logo in Canada. We maintain and are seeking additional registered trademarks, and we also rely on common law trademarks. Common law trademark protection typically continues where and for as long as the mark is used. Registered trademarks continue in each country for as long as the trademark is registered. We believe that we have certain know-how and trade secrets relating to our technology and product candidates. We rely on trade secrets to protect certain aspects of our technology related to our current and future product candidates.

Obtaining patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents that could be used to prevent or attempt to prevent us from commercializing our product candidates. If third parties prepare and file patent applications in the United States or other jurisdictions that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO or similar proceedings in other jurisdictions to determine the priority of invention.

Patent Term

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, a patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application ("PTA") or extended to account for term effectively lost as a result of the FDA regulatory review period ("PTE"), or both. In some cases, the term of a U.S. patent may be shortened by the filing of a terminal disclaimer that reduces its term to that of an earlier-expiring patent.

The term of a U.S. patent may be eligible for PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of an FDA-approved drug, an FDA-approved method of treatment using the drug, and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the earlier of five years beyond the non-extended expiration of the patent and 14 years from the date of the FDA approval of the drug. Some foreign jurisdictions, including Europe and Japan, also have patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. In the future, if and when our product candidates receive FDA approval, we expect, where possible, to apply for patent term extension on patents covering those products, their methods of use, and/or methods of manufacture.

Trade Secrets

In addition to patents, we may rely on trade secrets and know-how to develop and maintain our competitive position. Companies typically rely on trade secrets to protect aspects of their business that are not amenable to, or that they do not consider appropriate for,

patent protection. We protect trade secrets, if any, and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, and, where feasible, with consultants, scientific advisors, contractors and certain other entities with whom we do business. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also generally provide that all relevant inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, designed to guard against misappropriation of our proprietary information by third parties.

However, trade secrets can be difficult to protect. While we seek to protect our proprietary information, including trade secrets, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees and also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Competition

Our most advanced product candidate, MM120 ODT, is in Phase 3 development for GAD and MDD, with additional psychiatric indications under assessment and planning. Patients with GAD and MDD are typically treated with a variety of anxiolytic and antidepressant medications, including selective serotonin reuptake inhibitors, serotonin–norepinephrine reuptake inhibitors and benzodiazepines. A number of companies are developing product candidates intended for the treatment of anxiety and depressive disorders, including atai Life Sciences N.V. ("Atai"), Compass Pathways plc ("Compass"), Cybin, Inc. ("Cybin"), Lykos Therapeutics ("Lykos"), Johnson & Johnson ("J&J"), Otsuka Pharmaceutical Co. Ltd. ("Otsuka"), GH Research ("GH Research"), Beckley Psytech and others.

Cybin is currently evaluating CYB004 (a serotonin receptor agonist) in a Phase 2 trial for the treatment of GAD. In addition, Otsuka is currently conducting a Phase 2/3 clinical trial of ulotaront (SEP-363856), a trace amine-associated receptor 1 (TAAR1) agonist with 5-HT1A agonist activity, for the treatment of GAD and MDD.

Intra-Cellular Therapies ("Intra-Cellular") is currently developing multiple product candidates that are in various phases of development for the treatment of GAD and MDD, including CAPLYTA (lumateperone) as an adjunctive treatment for adults with MDD and ITI-1284 ODT-SL for GAD. In December 2024, Intra-Cellular announced the submission of a supplemental NDA to the FDA for CAPLYTA. On January 13, 2025, Intra-Cellular announced that it had reached an agreement to be acquired by J&J.

Atai is currently developing multiple product candidates that are in various phases of development for the treatment of psychiatric and substance use indications, including deuterated etifoxine (GRX-917) for anxiety disorders and VLS-01 (an oral transmucosal film formulation of N,N-dimethyltryptamine (DMT)) for treatment resistant depression ("TRD"). Compass is developing COMP360 (a proprietary formulation of psilocybin) that is in Phase 3 clinical trials for the treatment of TRD in adults and is being studied in other psychiatric indications (anorexia nervosa and post-traumatic stress disorder). GH Research is developing GH001 and GH002 that are in Phase 1/2 clinical trials for TRD and other psychiatric disorders. On February 3, 2025, GH Research announced that its Phase 2b trial for GH001 successfully met its primary endpoint.

In December 2023, Lykos announced that it had submitted an NDA to the FDA for its (+/-)-MDMA product candidate used in conjunction with psychological intervention for the treatment of post-traumatic stress disorder. In August 2024, Lykos announced that the FDA had issued a complete response letter for its NDA. Lykos has publicly stated that it is in the process of working with the FDA on a potential path forward for its product candidate.

If successfully developed and approved in the treatment of TRD in adults, MM120 ODT may also face competition from J&J's intranasal esketamine (SPRAVATO) approved for this indication, and from intravenous ketamine, which is not approved, however is used off label in the treatment of TRD in adults. In addition, MM120 ODT would likely face competition from Axsome Therapuetics Inc.'s ("Axsome") Auvelity, approved for the treatment of MDD. There are also many other public and private companies developing therapeutics from the psychedelic drug class at various stages of development, including certain short-acting psychedelic drugs.

Our other lead product candidate, MM402, an enantiomer of MDMA with selective serotonergic activity, is in Phase 1 clinical development for the treatment of core symptoms of ASD. If successfully developed and approved, MM402 may face competition from Atai, which has also indicated it is developing R-MDMA through one of its subsidiaries, and Lykos, which has a (+/-)-MDMA product candidate in clinical development for the treatment of social anxiety in the ASD population. In addition, in January 2024, Atai announced

positive topline data from its Phase 1 trial evaluating EMP-01, its orally administered formulation of R-MDMA, for Social Anxiety Disorder ("SAD") and has subsequently announced its intention to initiate a Phase 2 trial of EMP-01 for SAD. Other companies are also developing serotonergic therapies for the treatment of ASD or related indications. For example, Nova Mentis Life Science Corp and Mycrodose Therapeutics Inc. are collaborating on a transdermal psilocybin product candidate for the treatment of Fragile X syndrome.

More broadly, numerous pharmaceutical companies are developing or partnering to develop pharmaceutical products targeting the treatment of brain health disorders. This includes companies such as Novartis AG, Roche, Pfizer Inc., Biogen Inc., Jazz Pharmaceuticals plc, Johnson & Johnson, Sage Therapeutics, Inc., AbbVie Inc., Neumora Therapeutics, Inc., Praxis Precision Medicines and Biohaven Pharmaceutical Holding Co. Ltd., among many others. Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. We expect competition in the indications we are pursuing will focus on efficacy, safety, convenience, availability, and price. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Government Regulation

Government authorities in the U.S. at the federal, state and local level, the UK, the EU, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring/pharmacovigilance, safety and periodic reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed in a given jurisdiction, considerable data demonstrating its quality, safety and efficacy must be obtained and/or generated, organized into a format specific to each regulatory authority, submitted for review and the drug must be approved by the relevant regulatory authority or authorities.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject a company to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's delay or refusal to approve pending applications, withdrawal of an approval, a clinical hold on a clinical investigation, warning or untitled letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil penalties or criminal prosecution.

Certain product candidates we are developing contain Schedule I controlled substances, like lysergide or MDMA, as defined in the Controlled Substances Act ("CSA"). Our product candidates must be approved by the FDA through the NDA process, and will need to be rescheduled by the Drug Enforcement Administration ("DEA") and states, before they may be legally marketed in the U.S. The process required before a drug, including a drug containing a Schedule I substance, may be marketed in the U.S. requires substantial time, effort and financial resources and generally involves the following:

- Completion of extensive nonclinical studies and testing, in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations and applicable requirements for the human use of laboratory animals or other applicable regulations;

- Submission to the FDA of an Investigational New Drug Application ("IND") application, which must become effective before human clinical trials may begin;

- Approval by an independent institutional review board ("IRB"), or ethics committee representing each clinical trial site before each trial may be initiated;

- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, collectively referred to as good clinical practices ("GCP"), which establish standards for conducting,

recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety and well-being are protected, to establish the safety and efficacy of the proposed drug for each proposed indication;

- Submission to the FDA of an NDA for marketing approval of a new drug;
- A determination by the FDA within 60 days of its receipt of an NDA to accept and file the NDA for review;
- Satisfactory completion of a potential FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical and/or clinical trial sites that generated the data in support of the NDA;
- Payment of applicable user fees;
- FDA review and approval of the NDA, including agreement on post-marketing commitments, if applicable;
- Rescheduling of any Schedule I substance under the CSA and applicable state-controlled substance laws to Schedules II-V or equivalent categories at the state level, or out of the Schedules; and
- Implementation of a REMS program, if applicable, and conduct of any required Phase 4 studies or trials, and compliance with post-approval requirements, including ongoing monitoring and reporting of adverse events related to the product.

The data required to support an NDA are generated in two distinct development stages: nonclinical and clinical. For new chemical entities, the nonclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. Nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal laws and regulations, including, for animal studies, the Animal Welfare Act and GLP. The sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

IND Application

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. Some nonclinical testing may continue even after the IND is submitted, but an IND must become effective before human clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocols for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials, including whether subjects will be exposed to unreasonable health risks, and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is conducted in compliance with GCP, including review and approval by an independent ethics committee and compliance with informed consent principles, and FDA is able to validate the data from the study through an onsite inspection if deemed necessary.

Clinical Trials

The clinical stage of development involves the administration of the drug candidate to healthy volunteers or to patients with the disease or condition being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted in accordance with GCPs, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and

accurate, and that the rights, safety, and well-being of study participants are protected. GCPs include the requirement that all research subjects provide their informed consent for their participation in any given clinical trial. Clinical trials are conducted under protocols describing, among other details, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants, and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to 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. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials.

- Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials typically involve studies in patients afflicted with the target disease to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.

- Phase 3 clinical trials generally involve large numbers of patients afflicted with the target disease at multiple sites (typically from several hundred to several thousand subjects), and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval and labeling. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended for drugs intended for chronic dosing to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are generally used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 clinical trials or studies as a condition of approval of an NDA, for example, if additional safety data is needed.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, increased rates of serious suspected adverse events, or findings from other studies or from animal or in vitro testing that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. Success in one phase does not mean that the results will be observed in subsequent phases. Each phase may involve multiple studies. If concerns arise about the safety of the product candidate, the FDA or other regulatory authorities can stop clinical trials by placing them on a "clinical hold" pending receipt of additional data, which can result in a delay or termination of a clinical development program. The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the 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 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 or not a trial may move forward at designated check points based on access to certain data from the trial, and may recommend suspension of a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug 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 drug candidate and, among other things, we must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on its clinicaltrials.gov website. Sponsors or distributors of investigational products for the diagnosis, monitoring or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

NDA and FDA Review Process

After the completion of clinical trials of an investigational product candidate, FDA approval of an NDA must be obtained before commercial marketing of the product. The NDA must include results of nonclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling and other relevant information. The FDA reviews the NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure the product's identity, strength, quality and purity.

In addition, under the Pediatric Research Equity Act, certain NDAs or supplements to an NDA 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, as discussed in *Pediatric Trials* below.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each NDA must be accompanied by a user fee, unless subject to a waiver. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

The FDA reviews all NDAs submitted before it accepts them for filing, and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. If the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA aims to complete its initial review of an NDA and respond to the applicant within 10 months from the filing date for a standard NDA and, and within six months from the filing date for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will generally conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMP. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements and integrity of the data submitted in the NDA. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. For example, the advisory committee may recommend or the FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") program is necessary to ensure safe use of the product. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation process for an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

After the FDA evaluates an NDA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or one or more additional pivotal Phase 3 clinical trials, and/or other significant and time-consuming requirements related to clinical trials, non-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such additional data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. The FDA typically requires that certain contraindications, warnings or precautions be included in the product labeling. Even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the data submitted in the application, and the

FDA may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which may involve clinical trials designed to further assess a drug's safety and/or efficacy and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a REMS to ensure that the benefits of the product outweigh the risks. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if the FDA determines that a REMS is required. A REMS could include a medication guide to patients about the product's risks and benefits; a plan for communication to health care providers; or conditions on the product's prescribing or distribution referred to as elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any limitations on approval, marketing or use for any of our products could restrict the commercial promotion, distribution, prescription or dispensing of those products. Additionally, pharmaceutical products containing a Schedule I controlled substances must be rescheduled at the state and federal levels before commercial marketing, as described in *Controlled Substances* below. Once granted, product approvals may be withdrawn for non-compliance with regulatory requirements if problems occur following launch, or if FDA determines that the product is no longer safe or effective.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, may require submission and prior FDA approval of a supplemental application (or in some cases a new application) before the change can be implemented. A supplemental application for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing original marketing applications.

Expedited Development and Review Programs

The FDA has several programs that are intended to expedite or facilitate the process for reviewing new drugs that are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation and Breakthrough Therapy designation are two of these programs and apply to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug as a Fast Track product at any time during the development of the product on the basis that data demonstrate the potential to address an unmet medical need, and may request the FDA to designate the drug as a Breakthrough Therapy based on preliminary clinical evidence that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies, if available, as outlined in the FDA's programs. Under the Fast Track or Breakthrough Therapy expedited programs, the FDA may review sections of the marketing application on a rolling basis before the complete NDA is submitted if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. Even if a product receives a designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

Any product submitted to the FDA for marketing, including under a Fast Track or Breakthrough Therapy program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious condition and offers a significant improvement in the safety and effectiveness of treatment, diagnosis or prevention compared to marketed products. Significant improvement may be shown by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months from the date of the NDA filing.

A product may also be eligible for accelerated approval if the product is intended to treat a serious or life-threatening illness and provides a meaningful therapeutic benefit over existing treatments. Accelerated approval for a product means that it may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials to validate the surrogate endpoint or otherwise confirm the clinical benefit. If the FDA concludes that a drug granted accelerated approval can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the drug, such as:

- distribution restricted to certain facilities or physicians with special training or experience; or
- distribution conditioned on the performance of specified medical procedures.

The limitations imposed would be commensurate with the specific safety concerns presented by the drug. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but may expedite the development or approval process.

Pediatric Trials

The Food and Drug Administration Safety and Innovation Act ("FDASIA") amended the FDCA 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 submit an initial Pediatric Study Plan ("PSP"), within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. 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 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 non-clinical studies, early phase clinical trials, and/or other clinical development programs. The FDA, if it learns of new information, may also request that the sponsor amend the initial PSP.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, submitting periodic reports and providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements. Additionally, if approval is conditioned on post-marketing requirements, sponsors may need to conduct additional studies or clinical trials. Even if a REMS is not required at approval, FDA could determine that a REMS is necessary based on new safety data after approval.

In addition, pharmaceutical manufacturers must comply with advertising and promotional labeling requirements, which include, among others, standards for direct-to-consumer advertising, promotion to HCPs, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use.

FDA regulations also require that approved products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. NDA sponsors and their third-party manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, administrative enforcement, warning or untitled letters from the FDA, mandated corrective advertising or communications with doctors, and civil penalties or criminal prosecution, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, such as a REMS. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

After approval, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, or modifying a REMS the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional non-clinical studies and/or clinical trials. As with new NDAs, the review process may include FDA requests for additional information or clarification, and can ultimately result in denial or modification of the planned changes. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act and the Drug Supply Chain Security Act.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Department of Health and Human Services; the U.S. Department of Justice; the DEA; the Consumer Product Safety Commission; the Federal Trade Commission; the Occupational Safety and Health Administration; the Environmental Protection Agency; and state and local governments.

In the U.S., arrangements and interactions with healthcare professionals, third-party payors, patients and others will expose us to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other health care laws and regulations. These broadly applicable laws and regulations may constrain the business or financial arrangements or relationships through which we sell, market and distribute our approved product and any future products that may obtain marketing approval. In the U.S., federal and state health care laws and regulations that may affect our operations include:

- The federal Anti-Kickback Statute, which prohibits, among other things, any person, including a company marketing a prescription drug (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward the referral of an individual or purchase, lease or order, or the arranging for or recommending the purchase, lease, or order, of any item or service, for which payment may be made in whole or in part under a federal healthcare program, such as Medicare or Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, patients, purchasers and formulary managers on the other. The definition of "remuneration" under the federal Anti-Kickback Statute has been interpreted to include anything of value. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. 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 civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance. Violations of this law may be punishable by up to ten years in prison, criminal fines, damages, administrative civil money penalties, and exclusion from participation in federal healthcare programs.

- The federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim; or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by the federal government or as a qui tam action by a private individual in the name of the government. Many pharmaceutical manufacturers have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper activities. The government may deem companies to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for a False Claims Act violation may include three times the actual damages sustained by the government, plus significant civil penalties for each separate false or fraudulent claim, and the potential for exclusion from participation in federal healthcare programs.

- Numerous federal and state laws, including comprehensive data privacy laws, state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act and the California Consumer Privacy Act, as amended by the California Privacy Rights Act), govern the collection, storage, transfer, processing, generating, use, and disclosure and protection of health-related and other personal information. Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and

creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may result in additional compliance burdens for our clinical trials and necessitate changes to our services, information technologies, systems, and practices. Failure to comply with these laws and regulations could result in government enforcement actions and create liability, private litigation, or adverse publicity. In addition, we or our collaborators may obtain health information from third parties, such as hospitals, healthcare professionals, and research institutions, that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations (collectively, "HIPAA"). HIPAA imposes privacy and security obligations on covered entity HCPs, health plans, and healthcare clearinghouses, as well as their "business associates" – certain persons or entities that create, receive, maintain or transmit protected health information in connection with providing a service or performing a function on behalf of a covered entity. Although we are not directly subject to the HIPAA information privacy and security provisions – other than with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we or our agents knowingly obtain individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protection.

- The HIPAA fraud provisions, which impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services.

- The federal Physician Payment Sunshine Act, implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services (the "CMS"), the agency that administers the Medicare and Medicaid programs, information related to direct or indirect payments and other transfers of value to physicians, teaching hospitals and certain other HCPs (such as physicians assistants and nurse practitioners), as well as ownership and investment interests held in the company by physicians and their immediate family members.

- Analogous state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, regardless of the payor. We also will become subject to other state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to HCPs; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other HCPs or marketing expenditures; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Substantial resources are necessary to ensure that our business arrangements and interactions with health care professionals, third party payors, patients and others comply with applicable healthcare laws and regulations. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law, and if we are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, imprisonment, damages, fines, disgorgement, exclusion from government funded health care programs such as Medicare and Medicaid or the curtailment or restructuring of our operations. Any action against us for violation of these laws or regulations, 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.

Numerous other laws may apply to our products. Pricing and rebate programs may include, among other things, the Medicaid rebate requirements established under the U.S. Omnibus Budget Reconciliation Act of 1990, as amended, and requirements in the Patient Protection and Affordable Care Act (the "ACA"). Civil monetary penalties or other potential sanctions may be imposed for, among other things, a failure to pay required rebates or report required pricing data on a timely basis. If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Many states impose various requirements on pharmaceutical manufacturers, including to report development costs and pricing information when prices are increased, with potential penalties for late or faulty reporting. Products must meet applicable child-resistant packaging

requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The handling of any controlled substances must comply with the CSA, the Controlled Substances Import and Export Act and any applicable state-controlled substance laws, as discussed in *Controlled Substances* below.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, issuance of warning or untitled letters, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. 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. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Many of these laws differ from one another in significant ways and may not have the same effect, thus complicating compliance efforts. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health information, such as sensitive condition information or the health information of minors, which may be subject to additional protections. Compliance with these laws is difficult, constantly evolving, and time consuming. Changes in statutes, regulations or the interpretation of existing laws or regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

State Corporate Practice of Medicine Laws

The corporate practice of medicine and other learned profession laws, regulations and doctrines, which are enforced by most states, are intended to prevent unlicensed persons from interfering with or influencing a physician's or other medical professional's professional judgment and prohibiting the sharing of professional services income with non-professional or business interests. These laws vary from state to state and are subject to broad interpretation and enforcement by state regulators. A determination of non-compliance could lead to adverse judicial or administrative action against us, civil or criminal penalties, receipt of cease-and-desist orders from state regulators, loss of professional licenses, or a restructuring of our business arrangements with affiliated providers and our Centers of Excellence.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, if any, some of our 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 Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, or the testing phase, plus the time between the submission date of an NDA and the approval of that application, or the approval phase. This patent term restoration period may be reduced by the FDA if it finds that applicant did not act with due diligence during the testing phase or the approval phase. 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 or restoration. In the future, if circumstances permit, we intend to apply for restoration of patent term for one of our then owned or licensed patents, if any, 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. Even if, at the relevant time, we have a valid issued patent covering our product, we may not be granted an extension if we were, for example, to fail to apply within applicable deadlines, to fail to apply prior to expiration of relevant patents or otherwise to 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, and we do not have any other exclusivity, our competitors may obtain approval of competing products following our patent expiration and our ability to generate revenues could be materially adversely affected.

Some of our products may also be entitled to certain non-patent-related data exclusivity under the FDCA. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical

entity ("NCE"). 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, an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA may not be submitted by another company for another drug containing the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA Orange Book by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for a full 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, for new indications, dosages or strengths of an existing drug. Three-year exclusivity prevents the FDA from approving ANDAs and 505(b)(2) applications that rely on the information that served as the basis of granting three-year exclusivity. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations, and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Certain additional periods of exclusivity may be available if a product is indicated for use in a rare disease or condition or is studied for pediatric indications. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which the FDA has interpreted to preclude approving for seven years any other sponsor's application to market the same drug for the same use for which the drug has been granted orphan drug designation, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan exclusivity operates independently from other regulatory exclusivities and other protection against generic competition, including patents that we hold for our products. A sponsor of a product application that has received an orphan drug designation may also be granted tax incentives for clinical research undertaken to support the application.

Orphan drug exclusivity does not block approval of competing products intended for the orphan-protected indication but containing a different active moiety, or containing the same moiety but intended for a different use. Orphan product exclusivity that could block a competitor to one of our products also could block the approval of one of our products for seven years if a competitor obtains approval of the product containing the same moiety for the same orphan disease or condition.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. The FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which extends any existing regulatory exclusivity and patent periods by an additional six months if the sponsor conducts clinical trials in children in response to a Written Request from the FDA. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies.

European Union Drug Development

In the European Economic Area ("EEA") (which is comprised of 27 Member States of the EU plus Norway, Iceland and Liechtenstein), our future products may also be subject to extensive regulatory requirements. As in the U.S., medicinal products can only be marketed if a marketing authorization from the European Commission or the competent regulatory authorities of the EU Member State has been obtained.

Similar to the U.S., the various phases of non-clinical and clinical research in the EEA are subject to significant regulatory controls. Regulation (EU) No 536/2014 (the "EU Clinical Trials Regulation"), introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EEA, including a new coordinated procedure for authorization of clinical trials and increased obligations on clinical trial sponsors to publish clinical trial results.

In the EEA, pediatric data or a Pediatric Investigation Plan ("PIP"), or waiver, is required to have been agreed upon with the European Medicines Agency ("EMA"), prior to submission of a marketing authorization application to the EMA or the competent authorities of the EU Member States. In some EU countries, we may also be required to have an agreed PIP before we can begin enrolling pediatric patients in a clinical trial.

European Union Drug Review and Approval and Post-Marketing Requirements

In the EEA, medicinal products can only be commercialized after a related marketing authorization has been granted. Marketing authorization for medicinal products can be obtained through several different procedures. These are through a centralized, mutual recognition procedure, decentralized procedure, or national procedure (if marketing authorization is sought for a single EU Member

State). The centralized procedure allows a company to submit a single application to the EMA. If a related positive opinion is provided by the EMA, the European Commission will grant a centralized marketing authorization that is valid in all EU Member States and three of the four European Free Trade Associations countries (Iceland, Liechtenstein and Norway), all of whom make up the EEA.

The EU centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, medicinal products designated as orphan pursuant to Regulation (EC) No 141/2000, advanced therapy medicinal products ("ATMPs") and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance that is not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or for which grant of centralized marketing authorization is in the interest of patients in the EU.

The decentralized authorization procedure permits companies to file identical applications for authorization to several EU Member States simultaneously for a medicinal product that has not yet been authorized in any EU Member State. The competent authorities of a single EU Member State, the reference Member State, are appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned Member States, are subsequently required to grant marketing authorization for their territories on the basis of this assessment. The only exception to this is where an EU Member State considers that there are concerns of potential serious risk to public health related to authorization of the product. In these circumstances, the matter is submitted to the Heads of Medicines Agencies for review. The mutual recognition procedure allows companies that have a medicinal product already authorized in at least one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States.

The maximum timeframe for the evaluation of a marketing authorization application in the EU is 210 days, not including clock stops during which applicants respond to questions from the competent authority. The initial marketing authorization granted in the EU is valid for five years. The authorization may be renewed and valid for an unlimited period unless the national competent authority of an EU Member State or the European Commission decides on justified grounds to proceed with one additional five-year renewal period. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities of the EU Member States or the EMA.

The holder of an EU marketing authorization for a medicinal product must also comply with the EU's pharmacovigilance legislation. This includes requirements to conduct pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

Various requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients ("APIs"), including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States in which wholesale distributors carry out their activities. Marketing authorization holders and/or manufacturing authorization holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

In the EU, the advertising and promotion of medicinal products are subject to EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (the "SmPC"), as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Other applicable laws at the EU level and in the individual EU Member States also apply to the advertising and promotion of medicinal products, including laws that prohibit the direct-to-consumer advertising of prescription-only medicinal products and further limit or restrict the advertising and promotion of medicinal products to the general public and to health care professionals. Breaches of the rules governing the promotion of medicinal products in the EU could be penalized by civil, criminal or administrative penalties, which may include fines and imprisonment. Advertising of medicinal products that contain psychotropic and narcotic substances is in any case prohibited.

European Union Regulatory Data Exclusivity

The EU legislation governing grant of marketing authorization for medicinal products provides opportunities for market exclusivity. Upon grant of marketing authorization in the EU, innovative medicinal products generally benefit from eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies.

On April 26, 2023, the European Commission adopted a proposal for a new Directive and a new Regulation, collectively referred to as the "Pharmaceutical Package", which aims to revise and replace the existing EU pharmaceutical legislation in order to enhance the availability, accessibility and affordability of medicinal products across the EU. The current proposal proposes to reduce the eight years of data exclusivity to six years but allows for additional regulatory data protection up to 12 years if specific conditions are met (unmet medical need, new therapeutic indication with significant clinical benefit during protection period, etc.). As of January 2025, the legislative process remains ongoing. On April 10, 2024, the European Parliament adopted at first reading its position on the Commission's proposal. The next phase involves the Council of the EU's adoption of its position and the commencement of inter-institutional negotiations thereafter. Once an agreement has been reached between the Council of the EU and the European Parliament, the legislation will be formally adopted by the two bodies, it will be published in the Official Journal of the EU and will enter into force 20 days following publication. Its adoption is likely to occur in 2026, with implementation following thereafter.

European Union Medical Device Development, CE Marking and Marketing

On May 26, 2021, the Regulation (EU) 2017/745 on Medical Devices (the "MDR") entered into application, repealing and replacing both the Medical Devices Directive, and the Active Implantable Medical Devices. The MDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. Medical devices including medical device software ("MDSW") must comply with the General Safety and Performance Requirements ("GSPRs") set out in Annex I of the MDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, including MDSW, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the MDR and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low-risk medical devices (Class I with no measuring function, not reusable and which are not sterile), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the involvement of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality management system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity (the "Certificate") following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE Mark to its medical devices after having drawn up and signed a related EC Declaration of Conformity.

Besides its involvement in the initial conformity assessment procedure, the Notified Body is required to carry out an annual audit (surveillance audit) and randomly perform unannounced audits at least once every five years. The quality management system and technical documentation of manufacturers will be required to be recertified periodically, as CE Certificates of Conformity issued by a Notified Body remain valid only for the period indicated in them and in no case exceeding five years.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the devices during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. Manufacturers are required to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant GSPR. This level of clinical evidence must be appropriate in

view of the characteristics of the device and its intended purpose. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

After a device is placed on the market, it remains subject to significant regulatory requirements. The MDR also imposes post-marketing surveillance requirements which requires manufacturers to continuously and proactively monitor the performance and safety of their devices through implementation of a post-market surveillance system, in a manner that is proportionate to the risk class and appropriate for the type of their device. Once a device is on the EEA market, manufacturers must comply with certain vigilance requirements, such as the reporting of serious incidents and field safety corrective actions (even those occurring outside the EEA) to the relevant Competent Authorities. The Competent Authorities of each EU Member State oversee the implementation of the MDR within their jurisdiction.

Certain of our product candidates are designed to be delivered to patients by dedicated medical devices. In the EU, products that are a combination of a medicinal product and a medical device are regulated as either a medicinal product or a medical device, depending on which component has the primary mode of action.

Medical devices that incorporate as an integral part of a medicinal product that has an action ancillary to the action of the medical device are regulated as medical devices in accordance with the MDR. However, the quality, safety and usefulness of the medicinal product must also be verified as part of the device and a scientific opinion from a national competent authority of an EU Member State or from the EMA, depending on its nature and therapeutic intention, must be sought by the Notified Body regarding the quality and safety of the medicinal product, including the benefit or risk of its incorporation into the medical device. Where a medical device incorporates a medicinal product as an integral part of a single use drug delivery system, it is regulated as a medicinal product. In this case, the relevant GSPRs of the MDR will apply to the safety and performance of the device element.

Regulation of Medicinal Products and Medical Devices following the UK's Exit from the EU

Following the UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, the Medicines and Healthcare products Regulatory Agency (the "MHRA") is now the UK's standalone regulator. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement (the "EU-UK Agreement"). The EU-UK Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the EU-UK Agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the EU-UK Agreement.

Among the changes that occurred, Great Britain (England, Scotland and Wales) is now treated as a third country by the EU. Northern Ireland continues to follow the EU regulatory rules, subject to changes introduced under the Windsor Framework from January 1, 2025 (as set out below). As part of the EU-UK Agreement, the EU and the UK recognizes cGMP inspections carried out by the other party and the acceptance of official cGMP documents issued by the other party. The EU-UK Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. There is a list, including all EU/EEA countries, of approved countries for import into Great Britain which require no import testing or U.K. "qualified person" release certification, provided each batch has been certified by a qualified person in a listed country. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

The UK regulatory framework in relation to clinical trials is derived from previous EU legislation (as implemented into UK law, through secondary legislation). The Medicines for Human Use (Clinical Trial) Regulations 2004 ("UK CTR") set out the requirements for clinical trials conducted in Great Britain and the EU Clinical Trials Regulation sets out the requirements for clinical trials conducted in Northern Ireland. However, the MHRA remains the competent authority over clinical trials conducted in Great Britain and in Northern Ireland. As of January 1, 2022, all new clinical trial applications must be submitted for approval via the combined review process. The combined review process streamlines the approval process in that applicants submit a single application via the Integrated Research Application System, covering both its application for a clinical trial authorization and a research ethics committee opinion. If required, the combined review process can also be used to obtain Health Research Authority Approval.

Amendments to the UK CTR are expected in early 2026. On December 12, 2024, a statutory instrument to amend the UK CTR was laid before Parliament. Key amendments include: (i) proportional regulation of lower risk clinical trials and simplified consent-seeking requirements; (ii) additional transparency requirements; (iii) extended archival periods for trial master files from 5 years to 25 years;

and (iv) a sunset period of two years which will be triggered if no participants are enrolled into the trial within this period. The amendments will bring the UK CTR into closer alignment with the EU clinical trial regulations.

As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Until January 1, 2025, when the Windsor Framework took effect, Northern Ireland continued to be covered by the marketing authorizations granted by the European Commission. From January 1, 2025, a single marketing authorization now covers the whole of the UK and has replaced existing separate licenses for Great Britain and Northern Ireland. Marketing authorizations obtained under the EU centralized authorization procedure are no longer valid in Northern Ireland, and have been converted into a UK-wide marketing authorization. The Windsor Framework has also introduced UK only labelling changes and disapplied the EU Falsified Medicines Directive ("FMD") in Northern Ireland. However, EU law does continue to apply in Northern Ireland with respect to areas such as pharmacovigilance, manufacturing and distribution.

Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the UK. Since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures to obtain a marketing authorization to market products in the UK. Under the MHRA's International Reliance Procedure ("IRP"), the MHRA may take into account a decision to approve a medicine taken by the European Medicines Agency or an equivalent regulatory authority in the US, Canada, Switzerland, Australia, Singapore or Japan as part of an expedited marketing authorization process for that product for the UK.

Regarding medical devices, the MDR entered into application in the EU. However, the MDR is not applicable in the UK. In the UK, MDs are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which retains a regulatory framework similar to the framework set out by the MDD. As a result, there is some regulatory divergence in the UK from the EU.

In light of the fact, that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed ("UKCA") mark to replace the CE Mark for medical devices on the market in Great Britain (GB). Northern Ireland, however, continues to be covered by the EU MDR. CE Marks continue to be recognized in Great Britain for medical devices until June 30, 2028 (for medical devices compliant with the Medical Devices Directive) and June 30, 2030 (for medical devices compliant with the MDR), after these dates, an equivalent UKCA mark will become mandatory in Great Britain. Moreover, all medical devices, including CE Marked medical devices, must be registered with the MHRA, in order to be placed on the Great Britain market. The EU legal framework remains applicable in Northern Ireland (any products placed on the market in the NI must be compliant with EU law). The UK's departure from the EU has also impacted customs regulations and impacted timing and ease of shipments into the EU from the UK.

A number of changes to the UK MDR are in process, including on pre-market requirements and post-market surveillance requirements, each of which will be introduced into law under separate statutory instruments. The MHRA has consulted on future pre-market requirements for medical devices and sought views on key changes such as introducing an international reliance route, a new classification system for in vitro medical devices, and whether UKCA marking requirements should be relaxed. New regulations on pre-market requirements are expected to be passed into law and take effect in early 2026. New regulations on post-market surveillance requirements were laid before Parliament in October 2024 and are expected to take effect in summer 2025.

European Union Data Protection

EU Member States and other jurisdictions where we may in the future operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation ("EU GDPR"), which became operative on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the processing of personal data, including health data from clinical trials and adverse event reporting. Data Protection Authorities from the different EU Member States may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EEA. We may face fines or regulatory action if we violate the EU GDPR. For example, under the EU GDPR, companies may face warnings, compliance orders and fines of up to 20 million Euros or 4% of annual global revenue for the preceding financial year, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Companies that wish to export personal data outside of the EEA or the UK can rely on the European Commission's Standard Contractual Clauses ("SCCs") for transfers outside the EEA or the international data transfer agreement ("IDTA") or the international data transfer addendum to the European Commission's standard contractual clauses

for international data transfers for transfers ("Addendum") outside the UK. Taking into account the binding judgement of the European Court of Justice, in the case commonly referred to as "Schrems II", companies relying on SCCs are required to carry out a transfer risk assessment. In addition, on July 10, 2023 the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework. Under this framework, personal data can flow freely from the EU to U.S. companies that participate in the Data Privacy Framework. The GDPR has introduced additional data protection obligations that can have specific impact on the conduct of clinical trials in the EEA. This includes obligations concerning the rights of patients in relation to their personal data collected during the clinical trials and the need to conclude arrangements with clinical trials sites concerning data processing activities.

Regulation outside of the U.S. and EU

For other countries outside of the U.S. and EU, such as certain countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Approval by a regulatory authority in one jurisdiction does not guarantee approval by comparable regulatory authorities in other jurisdictions. If we fail to comply with applicable foreign regulatory requirements applicable to a given country, we may not be able to obtain regulatory approval for our product candidates in such country if we choose to seek such approval, or 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.

Coverage and Reimbursement

U.S. Healthcare Reform

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. federal government and state legislatures have shown significant interest in implementing drug pricing reform and cost-containment programs, including price controls, restrictions on reimbursement and utilization management requirements, such as requirements for substitution of generic products or therapeutic equivalents. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. For example, the Inflation Reduction Act (the "IRA"), among other things, (1) directs HHS to negotiate the price of certain units of certain single-source drugs and biologics covered under Medicare, (2) imposes certain rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and (3) makes changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and replaces the existing coverage gap discount program with a new manufacturer discount program (beginning in 2025). These provisions began to take effect progressively in fiscal year 2023 and have been subject to legal challenges. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs of pharmaceutical and biological products, including sometimes establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits and implementing marketing cost disclosure and transparency measures. Moreover, 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. We expect that the healthcare reform measures that have been adopted, and that may be adopted in the future, may result in more rigorous coverage criteria for healthcare products and services, which could result in additional downward pressure on pharmaceutical drug pricing.

Pharmaceutical Pricing and Reimbursement

Any product candidates we successfully commercialize, if approved, in the future depend on the availability and extent of coverage and reimbursement from third-party payors, which are increasingly reducing reimbursements for medical products and services. Decreases in third-party reimbursement for our products or a decision by a third-party payor not to cover a product could reduce HCP usage of our products and have a material adverse effect on our sales, results of operations and financial condition. In the U.S., HCPs are reimbursed for covered services and products through Medicare, Medicaid, and other government healthcare programs, as well as through commercial insurance and managed healthcare organizations. No uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, our products must be scheduled as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) before they can be commercially marketed.

In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the EU provides options for the EU Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade (arbitrage between low-priced and high-priced Member States), can further reduce prices.

The Health Technology Assessment ("HTA"), which is governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health, therapeutic, economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of the HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on HTA ("HTA Regulation"). The HTA Regulation aims to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The HTA Regulation was adopted in December 2021, entered into force on January 11, 2022 and started to apply from January 12, 2025. Under the HTA Regulation, EU Member States are required to use common HTA tools, methodologies, and procedures across the EU. Among others, the Regulation establishes an HTA coordination group, composed of national HTA bodies, which jointly conduct Joint Clinical Assessments ("JCAs") of new medicines and certain high-risk medical devices and introduces a single EU-level submission file for JCAs. However, the HTA Regulation focuses on the clinical aspects of HTA, i.e. the relative clinical effectiveness and relative clinical safety of a new health technology as compared with existing technologies, and, as such, individual EU Member States remain responsible for determining the overall value of a new health technology within their healthcare systems, as well as making pricing and reimbursement decisions.

In various EU Member States, we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative.

In the UK, new innovative products are subject to a health technology assessment process by the National Institute for Health and Care Excellence ("NICE") to determine whether they are cost effective and should be reimbursed by the National Health Service ("NHS"), the main provider of healthcare, in England and Wales. The Scottish Medicines Consortium makes this assessment for Scotland. The NHS is obliged to provide funding for products with a positive assessment outcome. Manufacturers of branded and biological medicines are also subject to either a voluntary scheme, known as the Voluntary Scheme for Branded Medicines Pricing and Access ("VPAG") or statutory scheme, under which they pay a rebate to the Department of Health and Social Care ("DHSC") on the sales of products to the NHS. A new VPAG was agreed by industry and Government and came into force on 1 January 2024, under which for the first time payments to the DHSC are calculated using different methods for newer medicines and older medicines, rather than the previous single rebate percentage that applied to all products.

Controlled Substances

The CSA and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, prescribe or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The CSA categorizes controlled substances into one of five schedules—Schedule I, II, III, IV or V—with varying qualifications for controlling in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be controlled as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V

substances presenting the lowest relative potential for abuse and dependence. Certain product candidates we are developing contain Schedule I controlled substances, like lysergide or MDMA, as defined in the CSA. Drug products approved by the FDA that contain Schedule I substances must be rescheduled to Schedules II-V by the DEA after FDA approval or, potentially, removed completely from the schedules for the product to be prescribed to patients in the United States. To reschedule a substance or product, the DEA must conduct notice-and-comment rulemaking, including issuing an interim final rule 90 days after the later of notification of FDA approval or DEA receipt of the HHS scheduling analysis and recommendation. Such action will be subject to public comment and requests for hearing. Rescheduling and submission of a supplemental application to FDA to update the labeling and packaging of the drug must occur before commercial marketing begins.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s).

Additionally, the DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers and distributors of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

The DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or procured in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Because the states are separate jurisdictions, they may separately schedule our product candidates. After FDA approval, states must also reschedule a drug product containing a Schedule I substance, which may occur automatically based on the federal action or may require the state to reschedule the product through rule making or a legislative action. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA or a state may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Legislation adopted at EU level in relation to establishment of different classes of substances is limited to the EU Regulations that define classes of precursors. These are Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors regulating intra-Community trade, the Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, the Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 supplementing the Regulation (EC) No 273/2004, the Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015 laying down rules in respect of the Regulation (EC) No 273/2004, and the Commission Delegated Regulation (EU) 2020/1737 amending Regulation (EC) 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances. While EU legislation does not establish different classes of narcotic or psychotropic substances, the EU has a pan-European system to rapidly detect, assess and respond to health and social threats caused by new psychoactive substances ("NPS"), under the procedures set out in the Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 as regards information exchange on, and an early warning system and risk assessment procedure for, NPS.

In the EU, controlled substances are largely governed by the national law of the individual EU Member States. EU Member States classify medicinal products and precursors according to the three UN Conventions of 1961, 1971 and 1988 controlling and supervising their legitimate scientific or medical use while taking into account the particular risks to public or individual health. It is within the competence of individual EU Member States to decide whether or not to add a specific substance to a Schedule. EU Member States may require entities and persons to obtain a national license to manufacture, import, export, distribute or offer a substance that has been added to a schedule of controlled substances. The related approach may differ from EU Member State to EU Member State. In the UK, the Misuse of Drugs Act 1971 and its subsequent amendments are the main legal framework for regulating controlled substances. The Act sets out the specific offenses related to the possession, supply, and production of controlled substances, as well as outlines the penalties that can be imposed for such offenses.

At the international level, the United Nations Single Convention on Narcotic Drugs of 1961 and the United Nations Convention on Psychotropic Substances are the primary legal instrument governing the control of controlled substances. The Convention requires States to adopt measures to prevent the misuse of controlled substances and also outlines the penalties to be imposed for the possession or supply of controlled substances in four Schedules. Additionally, the Convention sets out the criteria for classifying controlled substances, and the process for their international trade.

The World Health Organization (WHO) also plays an important role in regulating controlled substances through its Expert Committee on Drug Dependence (ECDD). The ECDD is responsible for assessing the risks and benefits of controlled substances and making recommendations to the WHO on their scheduling. The WHO publishes a regularly updated list of controlled substances, which includes their classification and international trade regulations.

These regulatory frameworks, and any changes to them, can introduce additional risks by making it difficult for manufacturers to access the substances they need to produce their products, and also makes them vulnerable to the risks of non-compliance with the regulations, which can further complicate the process of transporting, importing and exporting controlled substances.

Employees & Human Capital Resources

Our key human capital management objectives are to attract, retain and develop the highest quality talent. To support these objectives, our human resources programs are designed to develop talent to prepare them for critical roles and leadership positions for the future; reward and support employees through competitive pay and benefits; enhance our culture through efforts aimed at making the workplace more engaging and inclusive; and acquire talent and facilitate internal talent mobility to create a high-performing and diverse workforce.

As December 31, 2024, our personnel consists of 74 full-time employees, consisting of 50 in research and development and 24 in general and administrative. We also utilize consultants to assist us in our research and development projects and certain general and administrative functions. We are a remote-first company, meaning that substantially all of our employees and consultants work remotely. We have never had a work stoppage, and none of our employees are represented by a labor organization or under any collective bargaining arrangements. As of December 31, 2024, we consider our personnel relations to be good.

Corporate Information

We were incorporated under the laws of the Province of British Columbia in 2010. Our wholly-owned subsidiary, MindMed US, was incorporated in Delaware in 2019. Prior to February 27, 2020, our operations were conducted through MindMed US. In February 27, 2020, we completed a reverse takeover transaction (the "RTO Transaction") by way of a plan of arrangement under the Business Corporations Act (British Columbia) (the "BCBCA") among Broadway Gold Mining Ltd. ("Broadway"), Madison Metals Inc., Broadway Delaware Subco Inc. and Mind Medicine, Inc. ("MindMed US"). In connection with the RTO Transaction, immediately prior to the closing of the RTO Transaction, we, among other things, changed our name to our current name "Mind Medicine (MindMed) Our global headquarters are located at One World Trade Center, Suite 8500, New York, New York 10007. Our registered office in Canada is located at 1055 Dunsmuir Street, Suite 3000, Vancouver, British Columbia V7X 1K8. We also maintain offices in Durham, North Carolina.

Our common shares are traded on Nasdaq Global Select Market under the symbol "MNMD".

Available Information

Our website address is www.mindmed.co. In addition to the information about us contained in this Annual Report, information about us can be found on our website. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this Annual Report.

We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission ("SEC") and the Canadian securities regulators; annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. In addition, the SEC makes available at its website (www.sec.gov), free of charge, reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Any filings made to the Canadian securities regulators are available on SEDAR+ (www.sedarplus.ca).

RISK FACTORS

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report and those we may make from time to time. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common shares could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common shares.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, have not completed any pivotal clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2019, have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Our most advanced development candidate is MM120 ODT. We initiated our Phase 3 clinical program in GAD in December 2024 and we anticipate initiating our Phase 3 clinical program in MDD in the first half of 2025.

We have not yet demonstrated our ability to successfully initiate and complete any pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We are a clinical-stage pharmaceutical company and have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception, have not generated any revenue to date and have financed our operations principally through public offerings and private placements of our common shares and warrants to purchase our common shares, and through our credit facility with K2 HealthVentures LLC ("K2HV"). We incurred net losses of $108.7 million and $95.7 million for the years ended December 31, 2024 and December 31, 2023, respectively, and as of December 31, 2024, we had an accumulated deficit of $398.9 million. Our historical losses resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We intend to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance, market access, commercialization and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our product candidates are in various clinical, preclinical, discovery and research stages. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our expected losses, among other things, may continue to cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase substantially if and as we, among other things:

- continue the clinical development of our product candidates and other preclinical programs in GAD, MDD, ASD and other potential or future indications, including initiating additional and larger clinical trials;

- continue the training of healthcare practitioners who are qualified to deliver our product candidates in our clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval, including MM120 and MM402;
- seek additional indications for our product candidates and discover and develop any future product candidates, including product candidates in our digital medicine pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- experience heightened regulatory scrutiny;
- pursue necessary scheduling-related decisions to enable us to commercialize any future product candidates containing controlled substances for which we may obtain regulatory approval, including our MM120 and MM402 product candidates;
- experience animal toxicology issues significant enough for the FDA or other regulatory agencies to disallow investigation in humans;
- explore external business development opportunities through acquisitions, partnerships, co-development deals and/or licensing deals to add future product candidates and technologies to our portfolio;
- obtain, maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent or other intellectual property infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- experience any delays or encounter any issues with respect to any of the above, including studies that impede further development with unfavorable results, ambiguous trial results, safety issues or other regulatory challenges;
- expand our operations in the United States and potential other geographies in the future; and
- incur additional legal, accounting and other expenses associated with operating as a public company listed in the U.S., including expenses that may result due to securities litigation or shareholder activism.

To become and remain profitable, we will need to continue developing and eventually commercialize product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, training a sufficient number of qualified healthcare practitioners to deliver our product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, rescheduling product candidates that are currently characterized as Schedule I controlled substances and establishing marketing capabilities. Even if any of the product candidates that we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, or other comparable foreign authorities to perform studies or clinical trials in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of our product candidates, our expenses could increase beyond our current expectations and revenue could be further delayed.

Even if we or any future collaborators do generate sales, we may never achieve, sustain or increase profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our common shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses, investors may not receive any return on their investment and may lose their entire investment.

The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate

of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our common shares.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

In August 2023, we entered into a Loan and Security Agreement (the "Loan Agreement") with K2HV, as administrative agent and Canadian collateral agent for lenders thereunder (K2HV, and any other lender from time to time, the "Lenders"), and Ankura Trust Company, LLC, as collateral trustee for the Lenders. At closing, we borrowed $15.0 million in the first tranche under the Loan Agreement, and the second milestone-based tranche of $10.0 million was achieved and funded in the second quarter of 2024. We may borrow an additional $10.0 million based upon the achievement of certain time-based, clinical and regulatory milestones, and an additional $15.0 million upon our request, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders. Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets, other than certain intellectual property assets. The Loan Agreement includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our shareholders may consider beneficial. In addition, the Lenders could declare a default upon the occurrence of any event that it interprets could have material adverse effect, subject to the limitations specified in the Loan Agreement. Upon the occurrence and continuance of an event of default, the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Any declaration of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline. If we are liquidated, the rights of the Lenders to repayment would be senior to the rights of the holders of our common shares to receive any proceeds from the liquidation. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We have never generated revenue and may never be profitable.

We may never be able to develop or commercialize any marketable products or achieve profitability. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the acceptance of the product by physicians, payors and patients, the ability to obtain reimbursement and whether we own the commercial rights for that territory. Our growth strategy depends on our ability to generate revenue. In addition, if the number of addressable patients is not as anticipated, the indication or intended use approved by regulatory authorities is narrower than expected, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, and pursue or continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

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

Our business depends entirely on the successful discovery, development and commercialization of product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of MM120, MM402 and our other product candidates;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of MM120, MM402 and our other product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- achieving a successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more third parties;
- demonstrating a continued acceptable safety profile following any marketing approval of our product candidates;
- obtaining commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- rescheduling of product candidates that are controlled substances by the DEA, individual states or other comparable foreign authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, in the United States and in other jurisdictions;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our product candidates and advance our other programs. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA or other comparable foreign authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote MM120, MM402 or any other product candidate before we receive marketing approval from the FDA or other comparable foreign authorities. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2024, we had $273.7 million in cash and cash equivalents. Based on our current operating plan and anticipated R&D milestones, we expect our cash runway to extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD. Our estimate as to how long we expect our existing cash to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our shareholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the progress, timing and completion of preclinical testing and clinical trials for our product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to, including any delays as a result of animal toxicology issues or the need to conduct bioequivalence studies;
- the outcome and timing of any scheduling-related decisions by the DEA, individual states, and comparable foreign authorities;
- the number of potential future product candidates we identify and decide to develop, either internally through our research and development efforts or externally through acquisitions, licensing or other collaboration agreements;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our product candidates;
- the costs of developing sales and marketing capabilities to target public and private HCPs and clinic networks in major markets;
- the costs of training and certifying healthcare practitioners who are supporting or will support our clinical trials;
- generating and collecting data and obtaining intellectual property;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringements raised by third parties;

- the time and costs involved in obtaining regulatory approval for our product candidates, and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to our product candidates (such as MM120 and MM402) or any other product candidates;

- selling and marketing activities undertaken in connection with the potential commercialization of our product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;

- the amount of revenue, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and

- the costs of operating as a public company.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or our product candidates, or we may be unable to take advantage of future business opportunities. Changes in general market, economic, and political conditions could also adversely impact our ability to access capital as and when needed.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Sales of substantial amounts of our securities, or the availability of such securities for sale, as well as the issuance of substantial amounts of our common shares upon conversion of outstanding convertible equity securities, could adversely affect the prevailing market prices for our securities and dilute investors' earnings per share. A decline in the market prices of our securities could impair our ability to raise additional capital through the sale of securities should we desire to do so.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships, sales of assets and licensing arrangements. We, and indirectly, our shareholders, will bear the cost of issuing and servicing any such securities and of entering into and maintaining any such strategic partnerships or other arrangements. Because any decision by us to issue debt or equity securities in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future financing transactions. Subject to certain rules of the Nasdaq Stock Market ("Nasdaq"), the Board has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. Such additional issuances may involve the issuance of a significant number of common shares at prices less than the current market price for the common shares. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating and financing restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but may also limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses or other rights on unfavorable terms.

Risks Related to the Discovery, Development and Commercialization of our Product Candidates

We are dependent on the successful development of our product candidates. We cannot give any assurance that any of our product candidates will successfully complete clinical trials or receive regulatory approval, which is necessary before any product candidate can be commercialized.

We currently have no products that are approved for commercial sale, and we may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to the development of our product candidates. Accordingly, our business currently depends on the successful regulatory approval of our product candidates and the commercialization of our product candidates if they receive regulatory approval. We cannot be certain that MM120, MM402, or any of our other product candidates will receive regulatory approval or that our product candidates will be successfully commercialized even if they receive regulatory approval. If we are required to discontinue development of our product candidates, or if MM120 or MM402 does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of our product candidates is, and will remain, subject to comprehensive regulation by the FDA, and other foreign regulatory authorities. Failure to obtain regulatory approval in the United States or other jurisdictions will prevent us from commercializing and marketing our product candidates in such jurisdictions.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for our product candidates, any approval might contain significant limitations related to use, as well as restrictions for specified age groups, warnings, precautions, contraindications, and may be subject to additional monitoring and risk management plan requirements. In addition, we anticipate that any regulatory approval of our product candidates may include specific requirements or restrictions on the involvement or conduct of trained healthcare practitioners in the administration of our product candidates and we have not yet received any specific guidance from the FDA, or other regulatory bodies regarding such requirements or restrictions. Furthermore, even if we obtain regulatory approval for our product candidates, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, including securing availability of third-party treatment sites for the appropriate administration of our product candidates, securing adequate manufacturing, training and securing access to qualified healthcare practitioners, establishing a commercially viable pricing structure and obtaining coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

The success of our product candidates will depend on several factors, including the following:

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or clearance for conducting our clinical trials;
- successful patient enrollment in and completion of clinical trials;
- positive data from our clinical trials that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any product candidate is approved;
- rescheduling of any Schedule I substance under the CSA and applicable state-controlled substance laws to Schedules II-V or equivalent categories at the state level, or out of the Schedules, and implementation of a REMS, if applicable;
- entering into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection and/or regulatory exclusivity for our product candidates;

- successfully launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates benefits and uses, if approved, by patients, the medical community and third-party payors, and overcoming potential public controversy regarding our product candidates containing Scheduled I substances;
- maintaining a continued acceptable safety profile of our product candidates following approval;
- effectively competing with companies developing and commercializing other therapies in the indications which our product candidates targets;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- enforcing and defending intellectual property rights and claims; and
- complying with laws and regulations, including laws and regulations applicable to controlled substances.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive marketing approvals for our product candidates, we may not be able to continue our operations.

Our focus is on product candidates that are subject to controlled substance laws and regulations in the territories where the products are being developed and intended to be marketed, if approved, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations and our financial condition, both during clinical development and post approval, if any. In addition, the FDA and/or other regulatory bodies may require additional data, including with respect to abuse potential of our product candidates, before allowing us to commence a clinical trial or before approving any future marketing application we may submit.

In the United States, lysergide and MDMA are controlled as Schedule I substances under the CSA. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. For any product containing a Schedule I substance, such as lysergide or MDMA, to be available for commercial marketing in the United States, the substance or drug product containing the substance must be rescheduled under the CSA to Schedule II, III, IV or V or removed from the Schedules.

Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and special requirements for distribution, importation, and exportation. Pharmaceutical products approved for medicinal use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Even if approved by FDA, prescribing and dispensing of a controlled substance is subject to restrictions, with heightened restrictions for Schedule II controlled substances. For example, prescriptions for a Schedule II drug may not be refilled without a new prescription. Further, most, if not all, state laws in the United States classify lysergide and MDMA as Schedule I controlled substances. Commercial marketing in the United States will also require state scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are often dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while lysergide and MDMA are Schedule I controlled substances, products approved by the FDA for medical use in the United States that contain lysergide and/or MDMA must be descheduled or rescheduled to Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If MM120 and MM402 receive FDA approval, HHS and the DEA must complete a scheduling analysis and make a scheduling determination to deschedule or place either the substance or the drug product in a schedule other than Schedule I in order for them to be able to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the HHS's recommendation as to the appropriate schedule under the CSA. The rescheduling process requires the DEA to conduct notice-and-comment rulemaking, including issuing an interim final rule 90 days after the later of notice of FDA approval or DEA receipt of the HHS scheduling analysis and recommendation. Such action will be subject to public comment and requests for hearing. Even assuming our product candidates are controlled in Schedule II or lower at the federal level, such substances or products may require separate rescheduling or descheduling determinations under state laws and regulations.

If approved by the FDA, and if the finished dosage form of any of our product candidates is controlled as a Schedule II, III, or IV controlled substance under the CSA, such product candidate's manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will continue to be subject to a significant degree of regulation by the DEA. In addition, product candidates

containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including:

- **DEA registration and inspection of facilities**. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of our product candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

- **State-controlled substances laws.** Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates. While some states automatically schedule (or reschedule) a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

- **Clinical trials.** Because our product candidates fall into categories of substances that are "controlled substances", to conduct clinical trials on our product candidates in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our product candidates and to obtain our product candidates from our importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. We currently conduct our manufacturing or repackaging/relabeling of our product candidates or their active ingredients through our CDMOs in the United States and outside of the United States.

- **Importation.** If our product candidates are approved and classified as Schedule II, III or IV substances, an importer can import them for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our product candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration. If our product candidates are approved and classified as Schedule II controlled substances, federal law may prohibit the import of the substance for commercial purposes. If our product candidates are listed as a Schedule II substances, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances, including our product candidates, have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if we are unable to import our product candidates or any of their drug substances, our product candidates would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.

- **Manufacture in the United States.** If, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of our product candidates if approved, the active ingredient in the final dosage form is currently a Schedule I controlled substance and would be subject to such quotas as these substances could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredient in MM120, MM402, or any other product candidate, may not be sufficient to complete clinical trials or meet potential future commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or

production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

- **Distribution in the United States.** If our product candidates are scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute our product candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute our product candidates more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If our product candidates are Schedule II drugs, participants in our supply chain may have to maintain enhanced security with alarms and monitoring systems and they may be required to adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. In addition, our product candidates will likely be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial update. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

Our product candidates are controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding controlled substances and psychedelics may negatively influence the success of our product candidates.

Product candidates containing controlled substances have generated public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Opponents of these product candidates may seek to prevent or restrict marketing or demand withdrawal of any regulatory approvals. In addition, these opponents may generate negative publicity in an effort to persuade the medical community to reject these product candidates. For example, we may face media-communicated criticism directed at our clinical development program. In addition, adverse publicity related to lysergide or MDMA, or any other substance that underlies our product candidates or fall into the same drug or chemical class, which may be referred to as psychoactive or psychedelic drugs, may result from political or social opposition to controlled substances, misuse and abuse of controlled substances recreationally, or clinical trial conduct, including abuse by investigators. Adverse publicity of not only our product candidates, but also any similar controlled substances, may affect our clinical trials, potential regulatory approval, and the commercial success or market penetration achievable by our product candidates. For example, Lykos Therapeutics, another company developing a drug product candidate containing MDMA, recently faced significant public scrutiny and adverse publicity following negative public statements and allegations about clinical trial conduct made by clinical trial participants. Public controversy over the misuse or abuse potential of our or our competitor's product candidates may also harm our ability to recruit and retain clinical trial participants, negatively influence the recommendations of an FDA Advisory Committee, and/or result in the FDA requesting additional data related to the abuse potential of our product candidates, which could lead to delays in approval and increased research and development costs for our product candidates. Even if our product candidates are approved by the FDA, political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our product candidates.

We will be highly dependent upon consumer perceptions of the safety and quality of our product candidates if they are approved for commercial sale. We may face limited adoption if third-party treatment sites, HCPs, and patients are unwilling to try such a novel treatment and press coverage may influence their willingness. In addition to the history of negative media coverage regarding psychedelic substances, including lysergide and MDMA, recent and future public controversy related to clinical or recreational use of such substances, may affect the public's perception of our product candidates, which could adversely affect our business. We also could be adversely affected if any of our product candidates prove to be, or are asserted to be, harmful to patients, which could result in reputational harm. In addition, lysergide elicits intense psychological experiences, and this could deter patients from enrolling in clinical trials or choosing this course of treatment. Because of our dependence upon consumer perception, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our product candidates or any similar therapies distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations. Consumer perception can also be significantly influenced by scientific research or findings regarding the consumption of psychedelic inspired products. There can be no assurance that future scientific research or findings will be favorable to the market or any particular product, or consistent with earlier research or findings. Research in Canada, the U.S. and in other jurisdictions regarding the medical benefits, viability, safety, efficacy and dosing of psychedelic drugs remains limited. Although we believe that various articles, reports and studies support our beliefs regarding the medical benefits, viability, safety, efficacy and dosing of psychedelic inspired medicines, future research and clinical trials may prove such statements to be incorrect or could raise concerns. Future research studies and clinical trials may draw opposing conclusions to those stated in this report or reach negative conclusions regarding the medical benefits, viability, safety, efficacy, dosing, or other facts related to psychedelic inspired medicinal applications, which could have a material adverse effect on the demand for our products, and therefore on our business, prospects, revenue, results of operation and financial condition.

Future adverse events in research into GAD, MDD, ASD and other brain health disorders on which we focus our research efforts, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

Drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals, which would mean that we would be unable to commercialize our product candidates on a timely basis or at all, which will adversely affect our business.

Drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical and clinical trial process and we may never successfully progress a product candidate through clinical development.

Furthermore, we may experience delays in completing our ongoing preclinical studies and clinical trials and initiating or completing additional preclinical studies or clinical trials. We may also experience numerous unforeseen events during preclinical and clinical development that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- delays in or failure to obtain regulatory approval to commence or modify a trial, including the imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an Investigational New Drug Application ("IND"), or amendment, clinical trial application ("CTA"), or amendment, or equivalent application or amendment, as a result of a finding that the trial presents unreasonable risk to clinical trial participants or a negative finding from an inspection of our clinical trial operations or study sites, or the occurrence of a suspected, unexpected serious adverse reaction ("SUSAR"), or serious adverse reaction ("SAE"), during our clinical trials or IITs, using our product candidates;

- delays or denial of a researcher registration to one or more research sites that will allow those sites to handle and dispense our product candidates and to obtain our product candidates from our importer;

- delays in or failure to reach agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- delays in or inability to raise sufficient capital to fund research and development of our product candidates;

- delays in or failure to obtain IRB, or ethics committee approval at each site;

- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;

- failure to have patients complete a trial or return for post-treatment follow-up;

- clinical sites deviating from trial protocol or dropping out of a trial;

- inability to identify or maintain a sufficient number of trial sites, many of which may be already engaged in other clinical trials, including some that may be for competing product candidates with the same indication;

- challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in studies given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects;

- delay or failure in adding new clinical trial sites;

- ambiguous or negative interim results that are inconsistent with earlier results;

- availability of adequately trained HCPs and appropriate third-party clinical trial sites for our product candidates;

- sufficiency of any supporting digital services that may form part of the preparation, integration or long-term follow-up relating to any product candidate we develop;

- failure to contract for the manufacture of sufficient quantities of our product candidates for use in clinical trials in a timely manner;

- third-party actions claiming infringement by our investigational product candidates and other candidates or product candidates in clinical trials and obtaining injunctions interfering with our progress;

- safety or tolerability concerns which could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;

- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects or adverse events associated with a product candidate;

- failure of a product candidate to demonstrate any or enough of a benefit;

- methodological challenges associated with clinical research of psychotropic compounds that could hinder the interpretability or regulatory acceptability of clinical trial results, such as the effects of functional unblinding, expectation biases and protocols for patient support and monitoring during dosing sessions;

- changes in regulatory requirements, policies and guidelines;

- lower than anticipated retention rates of patients in clinical trials;

- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- delays in establishing the appropriate dosage levels in clinical trials;

- delays in our clinical trials related to public health crises like the COVID-19 pandemic, due to factors such as a decrease in the willingness or availability of patients to enroll in our clinical trials and challenges in procuring sufficient supplies of the underlying therapeutic substance;

- the quality or stability of the underlying therapeutic substance falling below acceptable standards;

- regulatory requirements to change the formulation of a product candidate, which can require expensive, risky and time-consuming bioequivalence studies;

- business interruptions resulting from macroeconomic conditions, including inflation and rising interest rates, geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, pandemics, or failures or significant downtime of our information technology systems resulting from cyber-attacks on such systems or otherwise; and

- changes in governmental regulations or administrative actions.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee (the "DRC"), or Data Safety Monitoring Board for such trial, as applicable, or by the FDA or other regulatory authorities or if the DEA registration of an investigator or site conducting the clinical trial is revoked. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including any SUSARs or SAEs which have in the past or may in the future occur in our trials or any IITs or other studies using lysergide, MDMA and any other substance that underlies our product candidates and those relating to the class to which lysergide, MDMA and other Schedule I controlled substances or any other product candidates belong, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of MM120, MM402 or any other product candidates, the

commercial prospects of our product candidates will be harmed, and our ability to generate revenue from any such product candidates will be delayed. In addition, any delays in completing our clinical trials will likely increase our costs, slow down MM120, MM402 or any other product candidate development and approval process and jeopardize our ability to commence sales and generate revenue. Moreover, if we make changes to our product candidates, we may need to conduct additional bioequivalence studies to bridge such modified product candidates to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Significant preclinical and clinical trial delays could also allow our competitors to bring therapies to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early.

Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of MM120, MM402, or any other product candidates that we may identify and pursue, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication. To receive regulatory approval for commercial sale, a product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. There is a high risk of failure and we may never succeed in developing marketable products. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

We cannot be certain that our clinical trials will be successful. Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. 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 clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our clinical trials are inconclusive with respect to the efficacy of MM120, MM402 and any other product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with MM120, MM402 and any other product candidates, we may be delayed in obtaining marketing approval, or we may never obtain marketing approval. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of MM120, MM402 and any other product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Even if our clinical trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do. Accordingly, more trials could be required before we submit any product candidates for approval. In addition, the FDA or other foreign regulatory authorities may change their recommendations for clinical trial conduct, such as for assessing abuse potential, like hallucinations, or the use of psychological support or psychotherapy in combination with a product candidate, for our product candidates or their drug class through regulation, guidance, or informal communications at any time, especially as drug development in this area increases. Because clinical trials take a significant period of time, we cannot assure that our trial design will comply with future FDA recommendations for clinical investigations involving psychedelic drugs. We may have already initiated or completed our clinical trials, and may need to amend our study protocol or conduct additional clinical trials as a result, which could be costly and time-consuming, and may significantly delay or limit our ability to commercialize our product candidates. For example, the FDA issued a draft guidance in June 2023 outlining clinical considerations for psychedelic drugs. There can be no assurances that the FDA will not change its recommendations in a revised guidance or final guidance, or issue a new draft guidance that could affect our development programs. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. Due to the inherent risk in the development of product substances, there is a significant likelihood that MM120, MM402 and any other product candidates will not successfully complete development and receive approval. Many other companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their product candidates. If we do not receive regulatory

approvals for MM120, MM402 or any other product candidates, we may not be able to continue our operations. Even if regulatory approval is secured for MM120, MM402 or any other product candidate, the terms of such approval may limit the scope and use of a specific product candidate, which may also limit its commercial potential.

Changes in our formulation of MM120 could have a material adverse effect on our business, financial condition and results of operations.

In August 2023, we entered into an exclusive licensing agreement with Catalent for its patented Zydis® orally ODT technology. Under the terms of the licensing agreement, Catalent granted us, among other things, access to its Zydis technology for the development of MM120. Zydis ODT is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water.

In our Phase 2 clinical trials for MM120, we used a formulation of MM120 that did not include ODT technology. In 2024, we completed a pharmacokinetics ("PK") bridging study to support the advancement of the MM120 ODT formulation into pivotal clinical trials, and we are using the MM120 ODT formulation in our Phase 3 clinical trials for GAD and MDD. This change in formulation could cause MM120 to perform differently, cause unforeseen side effects or affect the results of our Phase 3 clinical trials. This could delay completion of our Phase 3 clinical trials, require the conduct of additional bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs or delay or prevent the submission, or approval, of one or more NDAs for MM120. Such delays and costs could jeopardize our ability to, if approved, commercialize MM120 for GAD, MDD or other future indications, which could have a material adverse effect on our business, financial condition and results of operations.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. These data may not be sufficient to support regulatory submissions or approvals.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of patients have been enrolled, but before completion of the trial. Similarly, we may report topline or preliminary results of primary and key secondary endpoints before the final trial results are completed. Interim, topline and preliminary data from our clinical trials may change as more patient data or analyses become available. Preliminary, topline or interim data from our clinical trials are not necessarily predictive of final results. Interim, topline and preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies and independent organizations evaluating prescription drugs, such as the Institute for Clinical and Economic Review ("ICER"), may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general, and regulatory agencies may request further data from us. In addition, you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate. If the topline 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 MM120, MM402 or any other product candidate, our business, operating results, prospects or financial condition may be harmed.

We may not be able to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or similar regulatory authorities may not permit us to proceed in a timely manner, or at all.

Prior to commencing clinical trials in the United States or other jurisdictions, we may be required to have an allowed IND (or equivalent) for each product candidate and to file additional INDs prior to initiating any additional clinical trials for such product candidates. We believe that the data from previous studies will support the filing of additional INDs to enable us to undertake additional clinical trials of our product candidate portfolio as planned. However, submission of an IND (or equivalent) may not result in the FDA (or equivalent authorities) allowing further clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials (e.g., if the FDA places the trial on a clinical hold for safety reasons). Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the future. Failure to submit or have effective INDs (or equivalent) and commence or continue clinical programs will significantly limit our ability to generate revenue.

We may not achieve our publicly announced milestones according to schedule, or at all.

From time to time, we may announce the timing of certain events that we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials, or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business plan, financial condition or operating results and the trading price of our common shares.

The regulatory approval process of the FDA and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for any product candidates, our business will be substantially harmed.

We have not submitted a marketing authorization application to the FDA or other comparable foreign regulatory authority. Before obtaining regulatory approvals for the commercial sale of any product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities to set approval policies and data requirements. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Given the limited recent experience with clinical use of psychedelic drugs, it is likely the regulatory landscape will evolve, and could do so rapidly. We cannot guarantee that we will be able to or have the resources to adapt to changes regulatory requirements. We have not obtained regulatory approval for any of our product candidates. It is possible that none of our product candidates will ever obtain regulatory approval.

Any of our product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities or be precluded from commercial marketing for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with, question or request changes in the design or implementation of our clinical trials;
- the FDA or other comparable foreign regulatory authorities may determine that MM120, MM402 or any other product candidates are not safe and effective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA or other comparable foreign regulatory authorities may disagree with the design or implementation of our development programs, which may impact our ability to receive approvals for our product candidates;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a marketing authorization application with the FDA or other comparable foreign regulatory authority;

- the FDA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and

- the potential risk of our novel product candidates and delivery method, including the use of third-party clinical trial sites and healthcare practitioners.

This lengthy approval process, the unpredictability of future clinical trial results, and the potential influence of public opinion may result in our failing to obtain regulatory approval to market any product candidates, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process, including the data required for regulatory approval, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. If MM120, MM402 or any other product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process (such as priority review in the US), this will prevent such product candidate from obtaining approval on a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

In addition, even if we were to obtain approval, regulatory or pricing authorities may approve any product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios may have a negative impact on the commercial prospects for our product candidates and our business.

Even if MM120, MM402 or any other product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any such product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If the FDA or a comparable foreign regulatory authority approves MM120, MM402 or any other product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product candidates and underlying product substance will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, and with good clinical practices ("GCPs"), for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such product candidates. Additionally, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Later discovery of previously unknown problems with any approved product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of MM120, MM402 or any other product candidates, withdrawal of such products from the market, or product recalls;

- untitled and warning letters, or holds on clinical trials;

- refusal by the FDA or other foreign regulatory body to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;

- requirements to conduct post-marketing studies or clinical trials;

- restrictions on coverage by third-party payors;

- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

In addition, any regulatory approvals that we receive for MM120, MM402 or any other product candidates may also be subject to limitations on the approved indicated uses for which the product candidates may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of such product candidates. For instance, we believe that MM120, if approved, would be subject to a Risk Evaluation and Mitigation Strategy ("REMS") program, under the applicable FDA regulations and similar risk mitigation programs in other jurisdictions. REMS programs are costly and time-consuming for providers to comply with, involving high administrative burden, which could delay or limit our ability to commercialize our product candidates.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with our product candidates or our manufacture of an underlying product substance, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, require us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product candidates may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

Our product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of MM120, MM402 or any other product candidates or following approval, if any, we may need to abandon our development or commercialization of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials or result in clinical holds and could result in a more restrictive label, a requirement that we implement a REMS plan to ensure that the benefits of the product candidates outweigh its risks, or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. We or regulatory authorities may also learn of and take similar actions based on side effects related to MM120, MM402, any other product candidates, or similar compounds in studies not conducted by us, including in IITs or studies conducted by other sponsors, from spontaneous reports of use of these compounds outside of the clinical trial setting or from safety reports in literature.

The results of future clinical trials may show that MM120, MM402 or any other product candidates cause undesirable or unacceptable side effects or even death. There can be no assurance that deaths or serious side effects will not occur, even in a clinical setting. In the event serious side effects occur, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of MM120, MM402 or any other product candidates for any or all targeted indications. Nonclinical toxicology studies may also delay or limit clinical development, for example, by limiting the dosing duration and dose interval in clinical trials. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, because of the high variability in how different individuals react to lysergide, certain patients may have negative experiences with the treatment that could subject us to liability or, if publicized, reputational harm. Any of these occurrences may harm our business, financial condition and prospects significantly.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for MM120, MM402 or any other product candidates, we will have tested them in only a limited number of patients during our clinical trials. Clinical trials are by design based on a limited number of patients and of limited duration for exposure to the product candidates used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any such product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of MM120, MM402 or any other product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to such product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such trials may not be sufficient to identify when those events may occur.

Additionally, if our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including the following:

- regulatory authorities may require a recall of such product candidates or withdraw approvals of such product candidates and require us to take our approved product candidates, if any, off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS plan to ensure that the benefits of the product candidate outweigh its risks;
- we may be required to change the way the product candidates are administered, conduct additional clinical trials or change the labeling of the product candidate;
- we may be subject to limitations on how we may promote the product candidate;
- sales of the product candidates may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

Even if we obtain FDA approval for MM120, MM402 or any other product candidates, we may never obtain approval to commercialize any such product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries or jurisdictions regarding safety and effectiveness. Clinical trials conducted in one country or jurisdiction may not be accepted by regulatory authorities in other countries or jurisdictions, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs and require additional preclinical 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 product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets for our product candidates. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

There is a variety of risks associated with marketing our product candidates internationally, any of which could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA, Corruption of Foreign Public Officials Act ("CFPOA") or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Research and development of drugs targeting brain health disorders is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others.

Discovery and development of new drugs targeting brain health disorders are particularly difficult and time-consuming, evidenced by the higher failure rate for new drugs for brain health disorders compared with most other areas of drug discovery. Any such setbacks in our clinical development could have a material adverse effect on our business and operating results. In addition, our later stage clinical trials may present challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in trials given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects.

Due to the complexity of the human brain and the central nervous system, it can be difficult to predict and understand why a drug, including MM120, MM402 or any other product candidates, may have a positive effect on some patients but not others and why some individuals may react to the drug differently from others. Moreover, most of the patients we treat in clinical trials with MM120 and MM110 (prior to when we paused development of MM110) have previously been treated with other drugs or therapies. All of these factors may make it difficult for us and any regulatory authority to assess the prior use or the overall efficacy of our product candidates, including MM120 and MM402, and may result in the termination of a development program, or delay or limit our ability to obtain regulatory approval.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including:

- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;
- safety profile, to date, of the product candidate under study;
- the willingness or availability of patients to participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance, which may be influenced by negative publicity;
- the willingness or availability of patients to participate in our trials, including due to impacts of public health emergencies, as was seen during the COVID-19 pandemic;
- perceived risks and benefits of our approach to treating patients for the indication the clinical trial is investigating;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

In addition, any negative results we may report in clinical trials of MM120, MM402 or any other product candidates or results from companies investigating similar product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays in the enrollment for any clinical trial of MM120, MM402 or any other product candidates will likely increase our costs, slow down the approval process and delay or potentially jeopardize our ability to commence sales of our product candidates and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of MM120, MM402 or any other product candidates.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our product candidates on our own or with suitable collaborators.

While we are currently assembling a sales and marketing infrastructure, we have limited organizational experience in the sale or marketing of products. To achieve commercial success for any approved product candidates, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships.

If our product candidates are approved for commercial sale, we plan on establishing our own market access and commercialization capabilities in primary markets in North America and in the EU. In select geographies, we might also consider relying on the support of a contract sales organization ("CSO"), or enter into commercialization arrangements with companies with relevant commercialization capabilities. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our product candidates effectively or to market our product candidates effectively since we have limited organizational experience in the sales and marketing of products. In addition, recruiting and training a sales force is expensive and time-consuming, and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to train an adequate number of HCPs to meet the demand for psychedelic treatment sessions (including with MM120 and any other product candidate within the therapeutic class);
- the ability of HCPs to perform their roles consistently with our training and our guidelines for the administration of our product candidates;
- our inability to recruit, train and retain effective market access and commercial personnel;
- the inability of commercial personnel to obtain access to or educate adequate numbers of physicians on the benefits of prescribing MM120, MM402 or any other product candidates, if and when they are approved;
- our inability to identify a sufficient number of treatment centers in third-party treatment sites to meet the demands of our product candidates;
- the lack of complementary product candidates to be offered by our commercial personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent market access and commercial organization; and
- costs of market access and commercialization above those anticipated by us.

If we enter into arrangements with third parties to perform market access and commercial services for any approved product candidates, the revenue or the profitability of these revenues to us could be lower than if we were to commercialize any product candidates that we develop ourselves. Such collaborative arrangements may place the commercialization of any approved product candidates outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our product candidates or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. We may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to commercialize our product candidates effectively, to set up sufficient number of treatment centers in third-party treatment sites, or to recruit, train and retain adequate number of HCPs to administer our product candidates. In addition, we are exploring ways in which we can use digital technology to improve the patient experience and product outcomes of our product candidates. Commercialization partners may lack incentives to promote our digital technology and we may face difficulties in implementing our digital technologies in third-party treatment sites through such third parties.

If we do not establish commercial capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations.

The future commercial success of our product candidates will depend on the degree of market access and acceptance of our product candidates, if approved, among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large.

We may never have a product candidate that is commercially successful. To date, we have no product candidates authorized for marketing. Our product candidates require further clinical investigation, regulatory review, significant market access and marketing efforts and substantial investment before they can produce any revenue. Furthermore, if approved, our product candidates may not

achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large, and we may not become profitable. The level of acceptance we ultimately achieve may be affected by negative public perceptions and media coverage of psychedelic substances, including lysergide and MDMA. Because of this history, efforts to educate the medical community and third-party payors and health technologies assessment bodies on the benefits of product candidates may require significant resources and may never be successful, which would prevent us from generating significant revenue or becoming profitable. Market acceptance of our product candidates by healthcare professionals, patients, healthcare payors and health technology assessment bodies will depend on a number of factors, many of which are beyond our control, including, but not limited to, the following:

- acceptance by HCPs, patients and payors of each product candidate as safe, effective and cost-effective;
- changes in the standard of care for the targeted indications for any product candidate;
- the strength of sales, marketing and distribution support;
- potential product liability claims;
- the product candidate's relative convenience, ease of use, ease of administration and other perceived advantages over alternative therapies;
- the prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with our product candidate in relation to alternative treatments;
- the steps that prescribers and dispensers must take, given that our product candidates include a controlled substance, as well as the perceived risks based upon their controlled substance status;
- the ability to manufacture our product candidates in sufficient quantities and yields;
- the availability and amount of coverage and reimbursement from payors, and the willingness of patients to pay out of pocket in the absence of payor coverage or adequate reimbursement;
- the willingness of the target patient population to try, and of HCPs to prescribe, the product candidate;
- any potential unfavorable publicity, including negative publicity associated with recreational use or abuse of lysergide, MDMA or any other drugs from the same drug or chemical class, including during clinical trials;
- any restrictions on the use, sale or distribution of our product candidates, including through a REMS program; the extent to which product candidates are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether our product candidates are designated under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line product candidate.

If our product candidates fail to gain or maintain market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some product candidates achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue.

Our business and commercialization strategy depends on our ability to identify, qualify, prepare, certify and support third-party treatment sites offering any approved product candidate. If we are unable to do so, our commercialization prospects would be limited and our business, financial condition and results of operations would be harmed.

If we are able to commercialize our product candidates, our success will be dependent upon our ability to identify, qualify, prepare, certify and support third-party treatment sites that can offer and administer our product candidates. Our commercial model of delivering our product candidates will also involve third-party HCPs before, during and after the administration session, which will be hosted in one of the third-party treatment sites. We intend to commercialize our product candidates by building close relationships with qualified third-party treatments sites where these HCPs will administer our product candidates. Because we intend to work only with third-party sites and providers who agree to adhere strictly to the administration protocols described in labeling or a REMS program, we may face limitations on the number of sites available to administer our product candidates. Any such limitations could make it impracticable or impossible for some potential patients to access our product candidates, if approved, which could limit the overall size of our potential patient population and harm the results of our future operations. Although we plan to train and certify such third-party treatment sites, conduct further research on and continuously improve our administration protocols, we expect this to involve significant costs, time and resources, and our efforts may not be successful.

If we are unable to establish a sufficient network of third-party treatment sites certified under applicable standards, including regional, national, state or other applicable standards as needed to administer our product candidates, including the certifications that such third-party treatment sites may require, it would have a material adverse effect on our business and ability to grow and would adversely affect our results of operations and commercialization efforts. We expect the HCPs to be employed by the third-party treatment sites where the HCPs administer our product candidates. Third-party treatment sites could, for a number of reasons, demand higher payments for our product candidates or take other actions to increase their income from selling our product candidates, which could result in higher costs for payors and for our patients to get access to our product candidates. For example, legal regimes may require higher levels of licensure which force us to contract with third-party treatment sites that demand higher payment rates to administer our product candidates. In addition, third-party treatment sites may have difficulty meeting regulatory or accreditation requirements.

Given the novel nature of our product candidates, third-party treatment sites may face additional financial and administrative burdens in order to deliver any approved product candidate, including adhering to a REMS program in the United States or a Risk Management Program ("RMP") in the EU. The process for a third-party treatment site to become certified under a REMS program can be very costly and time-consuming, which could delay a third-party treatment site's ability to provide our product candidates and materially adversely affect our commercialization trajectory. Furthermore, third-party treatment sites will need to ensure that they have the necessary infrastructure and equipment in order to deliver our product candidates, such as adequate audio-visual equipment, ancillary equipment and sufficient administration rooms. This may deter third-party treatment sites from providing our product candidates and reduce our ability to expand our network and generate revenue. Our ability to develop and maintain satisfactory relationships with third-party treatment sites may otherwise be negatively impacted by other factors not associated with our operations and, in some instances, outside of our direct or indirect control, such as negative perceptions regarding the product use of lysergide, MDMA or other substances we use in our product candidates, changes in Medicare and/or Medicaid or commercial payors reimbursement levels and other pressures on HCPs and consolidation activity among hospitals, physician groups and the providers. Reimbursement levels may be inadequate to cover third-party treatment sites' costs of delivering our product candidates. The failure to maintain or to secure new cost-effective contracts with third-party treatment sites may result in a loss of or inability to grow our network of third-party treatment sites, patient base, higher costs to our patients and us, HCP network disruptions and/or difficulty in meeting regulatory or accreditation requirements, any of which could have a material adverse effect on our business, financial condition and results of operations.

We currently rely on qualified HCPs working at third-party clinical trial sites to administer our product candidates in our clinical trials and we expect this to continue upon approval, if any, of MM120, MM402 or any other product candidates. If third-party sites fail to recruit and retain a sufficient number of HCPs or effectively oversee their HCPs, our business, financial condition and results of operations would be materially harmed.

We currently administer our product candidates in our clinical trials through qualified third-party HCPs working at third-party clinical trial sites. However, there are currently not enough trained HCPs to carry out our product candidates at a commercial scale, and our efforts to facilitate training and certification programs for HCPs may be unsuccessful.

While we currently provide training to the HCPs and expect to continue providing trainings in the future (either directly or indirectly through third-party providers), we do not currently employ the HCPs who deliver our product candidates to patients and do not intend to do so in the future. Such HCPs are typically employed by third-party treatment sites. If our product candidates are approved for commercialization, third-party treatment sites may demand substantial financial resources from us to recruit and retain a team of qualified HCPs to administer our product candidates. If the third-party treatment sites fail to recruit, train and retain a sufficient number of HCPs, our ability to offer and administer our product candidates will be greatly harmed, which may in turn reduce the market

acceptance rate of our product candidates. If this occurs, our commercialization prospects would be negatively affected and our business, financial condition and results of operations would be harmed.

Although we currently provide training and expect to continue providing training to the HCPs (directly or through third-party providers), we generally rely on qualified and certified third-party treatment sites to manage the HCPs and monitor the administration of our product candidates and ensure that the administration process of our product candidates comply with dosing session guidelines. However, if not properly managed and supervised, there is a risk that HCPs may deviate from our dosing session guidelines, fail to follow the guidelines we have established, or abuse patients during administration sessions.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of product substances. Currently, we have no product candidates that have been approved for commercial sale; however, the use of our product candidates by us and our corporate collaborators in clinical trials, and the potential sale of any approved product candidates in the future, may expose us to liability claims. These claims might be made by patients who use our product candidates, HCPs, pharmaceutical companies, our corporate collaborators or other third parties that sell our product candidates. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If MM120, MM402 or any other product candidates causes adverse side effects during clinical trials or after regulatory approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with warnings that identify known potential adverse effects and describe which patients should not use MM120, MM402 or any other product candidates. Regardless of the merits or eventual outcome, liability claims may cause, among other things, the following:

- decreased demand for our product candidates due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from product sales; and
- the inability to commercialize our product candidates, if approved.

It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business, financial condition and results of operations could be materially adversely affected.

Liability claims resulting from any of the events described above could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulatory Approval and other Legal Compliance Matters

Lysergide, MDMA and other compounds used in our product candidates are listed as Schedule I controlled substances under the CSA in the U.S., and similar controlled substance legislation in other countries and any significant breaches in our compliance with these laws and regulations, or changes in the laws and regulations may result in interruptions to our development activity or business continuity.

Lysergide, MDMA and other compounds used in our product candidates are categorized as Schedule I controlled substances under the CSA, and are similarly categorized by most states and foreign governments. Even assuming that MM120, MM402 or any other product candidates containing lysergide, MDMA and other Schedule I controlled substances are approved and rescheduled by regulatory authorities to allow their commercial marketing, the ingredients in such product candidates could continue to be Schedule I, or the state or foreign equivalent. Violations of any U.S. federal, state, local or foreign laws or and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, cessation of business activities, divestiture, or prison time. This could have a material adverse effect on us, including on our reputation and ability to conduct our business, our financial position, operating results, profitability or liquidity or the market price of our publicly traded common shares. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation, defense or resolution of any such matters because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities.

Various federal, state, provincial and local laws govern our business in the jurisdictions in which we operate or currently plan to operate, and to which we export or currently plan to export our product candidates, including laws relating to health and safety, the conduct of our operations, and the production, storage, sale and distribution of our product candidates. Complying with these laws requires that we comply concurrently with complex federal, state, provincial and/or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure our compliance with these laws, we will need to invest significant financial and managerial resources. It is impossible for us to predict the cost of compliance with such laws or the effect they may have on our future operations. A failure to comply with these laws could negatively affect our business and harm our reputation. Changes to these laws could negatively affect our competitive position and the markets in which we operate, and there is no assurance that various levels of government in the jurisdictions in which we operate will not pass legislation or regulation that adversely impacts our business.

In addition, even if we or third parties were to conduct activities in compliance with U.S. federal, state or local laws or other foreign laws in which we conduct activities, potential enforcement proceedings could involve significant restrictions being imposed upon us or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on our business, revenue, operating results and financial condition as well as on our reputation and prospects, even if such proceedings conclude successfully in our favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of our key executives, the seizure of corporate assets, and consequently, our inability to continue business operations. Strict compliance with U.S. federal, state and local laws or other foreign laws and with respect to Schedule I substances, such as lysergide and MDMA does not absolve us of potential liability under U.S. federal, state and local laws or other foreign laws, nor provide a defense to any proceeding which may be brought against us. Any such proceedings brought against us may adversely affect our operations and financial performance.

Disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies, which could negatively impact our business.

The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel. Such changes and other disruptions at the FDA may increase the time to meet with the FDA and receive FDA feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, the current President Trump administration (the "Trump Administration") recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the Trump Administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. These budgetary pressures may reduce the FDA's ability to perform its responsibilities. In December 2024 and January 2025, we initiated our first and second Phase 3 clinical trials for our lead product candidate, MM120 ODT for the treatment of adults with GAD, and we plan to initiate our first Phase 3 clinical trial for MM120 ODT in MMD in the first half of 2025. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or marketing of MMD120 ODT, if approved, which could have a material adverse effect on our business.

Our business operations and our relationships with investigators, healthcare professionals, consultants, third-party payors and customers are currently or will be subject to U.S. federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, other healthcare laws and regulations and other foreign privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our relationships with investigators, healthcare professionals, customers and third-party payors, subject us to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute (the "federal Anti-Kickback Statute"). HCPs, physicians and others play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. These laws impact, among other things, our research activities and proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved product candidates, and other parties through which we market, sell and distribute our product candidates for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. These laws include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual or purchase, lease or order or the arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. The definition of "remuneration" under the federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. 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. Violations are subject to significant 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 that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (the "FCA"). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

- the federal civil and criminal false claims laws, such as the FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an

obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA 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 FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal civil monetary penalties laws, which impose civil penalties for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), health care fraud provisions, which imposes criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA health care fraud provisions without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain HCPs, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information and their covered subcontractors. 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;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistant and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous state laws and regulations, including the following: state anti-kickback and false claims laws, which may be broader in scope than their federal equivalents, and which may apply to our business practices, including research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to HCPs and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- the European and other foreign law equivalents of each of these laws, including reporting requirements detailing interactions with and payments to HCPs, and privacy-related requirements in the EU and other jurisdictions.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including licensing, extensive record-keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

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 HCPs, 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 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 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 HCPs 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 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, reputational harm, 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.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials (such as date of birth and initials), employee data, and sensitive third-party information. Our beta and development applications may include data from subject's mobile telephones and biometric wearables on subjects. Our information processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal information by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, HIPAA, as amended by the HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. To the extent that we act as a business associate to a HCP engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, such as restricting the use and disclosure of patient-identifiable health information, mandating the adoption of standards relating to the privacy and security of patient-identifiable health information, and requiring the reporting of certain security breaches to HCP customers with respect to such information. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative 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.

Additionally, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act ("CCPA") imposes obligations on businesses to which it applies. These obligations include, but are not limited to, data minimization obligations, providing specific disclosures in privacy notices and affording California consumers certain rights related to their personal information. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) and includes a private right of action for certain data breaches. Other states, including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut have enacted similar privacy laws or laws that broadly govern health data. These laws impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislation, on our business as additional information and guidance becomes available. Many states have also used existing consumer protection statutes to regulate companies' collection, use, and disclosure of personal information. If we become subject to these or other data privacy laws at the state, local or federal level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and regulators).

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, in Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, may apply to our operations. In addition, the EU GDPR and the United Kingdom's GDPR impose strict requirements for processing the personal information of individuals. For example, under the EU GDPR, government regulators may impose warnings or compliance orders, as well as fines of up to 20 million Euros or 4% of annual global revenue for the preceding financial year, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal information. The EU GDPR also provides that EU Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health information, which could result in differences between Member States, limit our ability to use and share personal information or could cause our costs to increase, and harm our business and financial condition.

Certain jurisdictions have enacted data localization laws and cross-border personal information transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal information to countries outside of the EEA. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal information outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal information. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal information out of the EEA. On July 10, 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework. Under this framework, personal data can flow freely from the EU to U.S. companies that participate in the Data Privacy Framework. Laws in the UK also restrict transfers of personal information outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal information protection. If we cannot implement a valid compliance mechanism for cross-border information transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe or elsewhere. The inability to import personal information to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal information processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

We are obligated to adhere to our contractual obligations and representations made in our policies related to data privacy and security. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, scrutiny and enforcement actions by regulators or other adverse consequences. Additionally, we may also be bound by contractual obligations related to data privacy and security with our partners or CROs, and our efforts to comply with such obligations may not be successful.

Laws, regulations, standards and related to data privacy and security are quickly changing, creating some uncertainty as to the effective future legal framework and our obligations. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times not meet all obligations (or be perceived to have not met our obligations). Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government scrutiny or enforcement actions (e.g., investigations, fines, civil and criminal penalties (including imprisonment of company officials), audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; restrictions on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those product candidates 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 our product candidates, if approved. Our products must be scheduled as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) before they can be commercially marketed. Our ability to achieve acceptable levels of coverage and reimbursement for product candidates by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaboration partners to invest in the development of our product candidates. There is limited clinical data on the long-term efficacy of lysergide or MDMA on treating brain health disorders. Certain patients may need repeated treatments over their lifetime to avoid or re-treat a relapse of their disorder. This may increase treatment costs, making it more difficult for us to secure reimbursement. Even if we obtain coverage for a given product candidate by third-party payors, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients may find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product candidate that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors are increasingly challenging prices charged for product substances and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive product candidate is available. It is possible that a third-party payor may consider our current product candidates as substitutable and only offer to reimburse patients for the less expensive drugs. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed therapies at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on product candidates that we may develop.

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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved therapies. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. 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. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug therapies exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug therapies 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 at short notice, and we believe that changes in these rules and regulations are likely.

We intend to seek approval to market MM120, MM402 and other product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions.

In some foreign countries, particularly certain countries in Europe, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical therapies are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical therapies but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount 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.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU-wide, law and policy. The medicines regulatory regime in respect of the EU applies to the EEA, which comprises the EU Member States as well as Norway, Iceland and Liechtenstein. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of therapies in that context. In general, however, the healthcare budgetary constraints in many EU Member States have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with increasing EU and national regulatory burdens on those wishing to develop and market therapies, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any product candidates for which we obtain marketing approval.

EU pharmaceutical legislation may materially affect our ability to market and receive coverage for our product candidates in the EU Member States. On April 26, 2023, the European Commission adopted a proposal for a new Directive and a new Regulation to revise and replace the existing EU pharmaceutical legislation (the Regulation 726/2004 and the Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively). The European Commission's proposal is currently being discussed by the European Parliament and the Council of the EU. On April 10, 2024, the European Parliament adopted its position on the proposals, the legislative processes of which are expected to continue in 2025 and beyond.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal therapies is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and in respect of the UK (which is no longer a member of the EU), the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in individual EU Member States and the particular requirements can therefore vary widely amongst the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including in many EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, individual EU Member States could restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU

Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. An EU Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost- effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Moreover, the HTA Regulation of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. The outcome of an HTA Regulation will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA Regulation of the specific medicinal product currently varies between EU Member States. It is difficult to predict at this time what third party payors and governmental authorities will decide with respect to the coverage and reimbursement for our product candidates.

There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, therapies launched in the EU and UK do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our product candidates is unavailable or limited in scope or amount, our revenue from sales and the potential profitability of our product candidates in those countries would be negatively affected.

Moreover, increasing efforts by governmental and third-party payors in the EU, the UK, the United States and elsewhere to cap or reduce healthcare costs may cause such organizations to limit coverage and the level of reimbursement for newly approved therapies and, as a result, they may not cover or provide adequate payment for our product candidates. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific therapies. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new therapies.

Enacted and future legislation may increase the difficulty of commercializing our product candidates and affect the prices we may charge for such product candidates.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Among other things, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things, (1) directs HHS to negotiate the price of certain units of certain single-source drugs and biologics covered under Medicare, (2) imposes certain rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and (3) makes changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and replaces the existing coverage gap discount program with a new manufacturer discount program (beginning in 2025). These provisions began to take effect in fiscal year 2023 and are expected to have a significant impact on the pharmaceutical industry, and have been subject to legal challenges. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

On the state level, local governments have been very aggressive in passing legislation and implementing 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. Additionally, some individual states have begun establishing Prescription Drug Affordability Boards to review high-cost drugs and, in some cases, set upper payment limits. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition 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 products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our investigational product candidates, our business may be materially harmed.

In the United States, if all maintenance fees are paid on time, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our investigational product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive therapies. Given the amount of time required for the development, testing and regulatory review of new investigational therapies, patents protecting such candidates and concomitant therapies might expire before or shortly after such candidates and concomitant therapies are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing therapies similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of MM120, MM402 or any other product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and similar legislation in the EU. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term loss during product development and the FDA regulatory review process. The 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 of manufacturing it may be extended. However, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will not be lengthened and third parties, including our competitors, may obtain approval to market competing therapies sooner than we expect. As a result, our revenue from applicable product candidates could be materially reduced and our business, financial condition, results of operations, and prospects could be materially harmed.

We could experience difficulty enforcing our contracts.

Due to the nature of our business and the fact that our contracts involve certain substances whose usage is not legal under U.S. federal law and in certain other jurisdictions, we may face difficulties in enforcing our contracts in U.S. federal and state courts. The inability to enforce any of our contracts could have a material adverse effect on our business, prospects, financial condition and results of operations.

In order to manage our contracts with contractors, we ensure that such contractors are appropriately licensed at the state and federal level in the United States and at the appropriate level in other jurisdictions. Were such contractors to operate outside the terms of these licenses, we may experience an adverse effect on our business, including the pace of development of our product candidates.

Investors in certain jurisdictions may have difficulty in enforcing judgments and effecting the service of process on us.

The enforcement by investors of civil liabilities under the United States federal or state securities laws may be affected adversely by the fact that we are incorporated under the laws of the Province of British Columbia. It may not be possible for investors to enforce judgments obtained in the United States courts against us based upon the civil liability provisions of United States federal securities laws or the securities laws of any state of the United States.

There is some doubt as to whether a judgment of a United States court based solely upon the civil liability provisions of United States federal or state securities laws would be enforceable in Canada against us. There is also doubt as to whether an original action could be brought in Canada against us to enforce liabilities based solely upon United States federal or state securities laws.

In addition, all of our directors and officers reside outside of Canada. Some or all of the assets of such persons may be located outside of Canada. Therefore, it may not be possible for investors to collect or to enforce judgments obtained in Canadian courts predicated upon the civil liability provisions of applicable Canadian securities laws against such persons. Moreover, it may not be possible for investors to effect service of process within Canada upon such persons.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the significant number of brain health disorders our products are being developed to treat, and we intend to utilize appropriate social media in connection with our

commercialization efforts following approval of our product candidates. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to identify the comment and comply with applicable adverse event reporting obligations. Additionally, we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to FDA restrictions on advertising and promoting unapproved new drugs or other foreign governmental restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

The production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions.

Our product candidates contain controlled substances, including psychedelic substances, which are subject to strict legal requirements in certain jurisdictions where we will produce and sell our products. Certain jurisdictions may not allow the use or production of the substances included in our products, nor provide any possibilities for an exemption or regulatory approval that could allow for the lawful use or production of such substances. In addition, these jurisdictions may prohibit any form of contributing to the production or use of these drugs and may also directly or indirectly prohibit the receipt of any benefits following from the production and sale of these substances. Under circumstances, this may have consequences for the legality of the purchase of our shares or receipt of dividends in or from foreign jurisdictions.

If certain foreign authorities consider it illegal to invest in our company, this will negatively affect the possibility of commercializing and generating revenue in the country of interest. Any investigations of authorities against foreign investors could generate negative publicity. We cannot predict the likelihood of foreign authorities taking such a point of view or taking any actions against investors in certain jurisdictions.

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

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

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

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

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act ("FCPA"), Corruption of Foreign Public Officials Act (Canada) ("CFPOA") and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S., Canadian and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA, CFPOA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA and CFPOA generally prohibit companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a government official in order to influence official action or otherwise obtain or retain business. The FCPA and CFPOA also require 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. and non-Canadian. 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. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or 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, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products may be subject to U.S., Canadian and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. and Canadian export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. and Canadian sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our product candidates or limitation on our ability to export or sell our product candidates would likely adversely affect our business.

Risks Related to Employee Matters, Managing our Growth and Other Risks Related to our Business

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. If we are unable to maintain consulting relationships with our scientific and clinical advisors or if they provide services to our competitors, our development and commercialization efforts will be impaired, and our business will be significantly harmed.

We face competition from other biotechnology and pharmaceutical companies and our financial condition and operations will suffer if we fail to effectively compete.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors include large, well-established pharmaceutical companies, biotechnology companies, academic and research institutions developing products for the same indications we are targeting and competitors with existing marketed therapies.

Many other companies are developing or commercializing therapies to treat the same diseases or indications for which our product candidates may be useful. Many of our competitors have substantially greater financial, technical and human resources than we do, and have significantly greater experience than us in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly than we do. Our ability to compete successfully will largely depend on: (1) the efficacy and safety profile of our product candidates relative to marketed products and other product candidates in development; (2) our ability to develop and maintain a competitive position in the product categories and technologies on which it focuses; (3) the time it takes for our product candidates to complete clinical development and receive marketing approval; (4) our ability to obtain required regulatory approvals; (5) our ability to commercialize any of our product candidates that receive regulatory approval; (6) our ability to establish, maintain and protect intellectual property rights related to our product candidates; and (7) acceptance of any of our product candidates that receive regulatory approval by physicians and other HCPs and payers.

Competitors have developed and may develop technologies and compounds that could be the basis for products that challenge MM120 ODT, MM402 or other product candidates we are developing. Some of those products may have an entirely different approach or means of accomplishing the desired product effect than our product candidates and may be more effective or less costly than our product candidates. The success of our competitors and their product candidates relative to our product candidates could have a material adverse effect on the development programs for MM120 ODT, MM402 or other product candidates, as they may impact our ability to raise additional capital, on favorable terms or at all, and our ability to obtain necessary regulatory approvals.

If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will substantially suffer.

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

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

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

In order to successfully implement our plans and strategies, we will need to increase the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2024, we had 74 full-time employees. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the FDA and other comparable foreign regulatory agencies' review process for MM120 ODT, MM402 or any other product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize MM120 ODT, MM402 or other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of MM120 ODT, MM402 or any other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize MM120 ODT, MM402 or other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive information, including personal information (such as health-related information), data related to clinical trials, intellectual property, and trade secrets. We may rely upon third-party service providers and technologies to operate critical business systems to process such information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive

sensitive information with or from third parties. Our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel or third parties authorized to access our systems, sophisticated nation-states, and nation-state-supported actors now engage in attacks. We and the third parties upon which we rely may be subject to a variety of evolving threats, including social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel or authorized third-party misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of information or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a cybersecurity incident or disruption to our information technology systems or the third-party information technology systems that support us and our services. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. For example, we have employees and consultants upon which we rely to support our business located in geographical proximity to unstable regions and regions experiencing (or expected to experience) geopolitical or other conflicts, such as consultants in Slovakia, a country that borders Ukraine which was attacked by Russia in February 2022 through various means, including cyberattacks.

Any of the previously identified or similar threats could cause a cybersecurity incident or other interruption. A cybersecurity incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to information. A cybersecurity incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against cybersecurity incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of third parties upon which we rely (including sites performing our clinical trials), there can be no assurance that these measures will be effective or that a court or regulatory authority will consider them to be appropriate or reasonable. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a cybersecurity incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified potential vulnerabilities. Additionally, 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 data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of cybersecurity incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a cybersecurity incident or are perceived to have experienced a cybersecurity incident, we may experience adverse consequences. These consequences may include: government scrutiny or enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of information); financial loss; delays in reporting our financial results; and other similar harms. Cybersecurity incidents and attendant consequences may cause customers to stop using our services, deter new clinical trial participants from participating in our services, and negatively impact our ability to grow and operate our business.

Risks Related to our Intellectual Property

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.

Our commercial success depends in part on 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 patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, reexamination, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous 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 product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable

intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Furthermore, as the patent landscape is crowded and highly competitive, 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 one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that patent searches, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third-party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

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

Similarly, 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the market price of common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

We employ individuals and retain independent contractors and consultants who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, independent contractors, consultants, collaborators and other third

parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such persons' former companies or other third parties. We may also be subject to claims that such persons or other third parties have an ownership interest in our intellectual property. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. 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.

In addition, while we require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

If we are unable to obtain and maintain effective patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets

We rely upon a combination of patents, trade secret protection, trademarks, and confidentiality agreements to protect the intellectual property related to our product candidates and development programs. Our success depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our present and future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our present or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any present or future product candidates or methods of using such. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent position of biopharmaceutical companies are generally uncertain and involve complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. The pending patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries for many reasons. Our pending and future patent applications may not result in patents being issued which protect

our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO") or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

Filing, prosecuting, defending and enforcing patents and trademarks on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent or trademark applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions and we may not be able to use our trademarks in all countries or prevent others from using or registering similar trademarks. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents 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.

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, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, 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. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. 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.

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

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We

seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we require all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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 harm our business. 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.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other 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 are party to a license agreement with Catalent, pursuant to which we were granted an exclusive license to use their Zydis technology in the development of MM120. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. In the event we breach any of our obligations under these agreements, we may incur significant liability to our research and licensing partners. Disputes may arise regarding intellectual property subject to a research licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and our collaborators;

- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.

In addition, our license agreement with Catalent imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology, and could compromise our development and commercialization efforts for our product candidates.

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

We expect to rely on trademarks as one means to distinguish our company's name and logo, as well as to distinguish the name and logos used with any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. For example, our U.S. trademark registration for MINDMED covers a narrower list of goods than we initially sought to include in the registration because the USPTO cited a third-party trademark application as an obstacle to registration with a broader list of goods and services. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

Under U.S. law, registration of a trademark requires lawful use of the mark in commerce. The USPTO may determine that our use of the trademark for our goods and services does not meet the statutory requirements for lawful use in commerce for registering a trademark if, for example, our products remain on Schedule I of the CSA. Consequently, the USPTO may refuse to register our trademarks, and existing registrations could be subject to cancellation. Furthermore, our ability to enforce our trademarks in U.S. federal courts or to prevent others from using similar marks may be limited due to these federal restrictions. This could lead to increased risks of infringement, dilution of our brand, and legal disputes that are difficult to resolve favorably. We may face analogous restrictions on protecting and enforcing trademarks in other jurisdictions internationally, and the requirements for lawful use of trademarks vary from country to country.

The cost to us of any trademark litigation or other trademark proceeding such as an opposition or cancellation action, even if resolved in our favor, could be substantial. Trademark litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of trademark litigation or other proceedings could impair our ability to compete in the marketplace.

In addition, any proprietary name we propose to use with our current or any other product candidate 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 the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Risks Related to our Dependence on Third Parties

We rely on third parties to supply and manufacture the MM120 ODT, MM402 and our other product candidates, and we will rely on third parties to manufacture these substances for commercial supply, if approved. If any third-party provider fails to meet its obligations manufacturing our product candidates, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substances and the commercialization of any product candidates, if approved, could be stopped, delayed or made commercially unviable, less profitable or may result in enforcement actions against us.

We do not currently have, nor do we plan to acquire, the infrastructure or capability necessary to manufacture MM120, MM402 or any other product candidates, including the lysergide, R(-)-MDMA or other controlled substances incorporated into such product candidates. We rely on, and expect to continue to rely on, CDMOs, for the development, manufacture and production of the lysergide used in our product candidates administered in our clinical trials and will continue to rely on such CDMOs for the development, manufacture, testing and production of any commercial supply, if our product candidates are approved. Currently, we engage with multiple CDMOs for all activities relating to the development, manufacture and production of all our product candidates including API, bulk drug product, and final drug product. Reliance on third-party providers, such as CDMOs, exposes us to more risk than if we were to manufacture our product candidates at our own facilities. While we subject our suppliers of MM120, MM402 or any of our other product candidates, including our current supplier of active pharmaceutical ingredient, to strict manufacturing requirements and rigorous testing requirements in order to ensure compliance with cGMP and other manufacturing regulations, such suppliers are still subject to inspection by the FDA and other applicable regulatory authorities and there can be no assurance that they are in compliance with all applicable regulations. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of MM120, MM402 or any other product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of MM120, MM402 or any other product candidates and harm our business and results of operations.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for MM120 ODT, MM402 or any other product candidates, we could experience delays in our research or planned clinical studies or commercialization. In addition, quality issues may arise during scale-up activities. We could be unable to find alternative suppliers of acceptable capability and quality, in the appropriate volumes and at an acceptable cost. For example, we have engaged a single supplier for the production of lysergide. Because lysergide is a controlled substance and subject to increased regulation resulting from that classification, if we are unable to rely on our current supplier for lysergide, we may experience delays or increased costs in obtaining an alternative provider or we may be unable to find an alternative supplier on acceptable terms. Our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, may significantly delay our preclinical studies and clinical trials and the commercialization of our product candidates, if approved, which would materially adversely affect our business, prospects, financial condition and results of operations.

In complying with the manufacturing requirements of the FDA, the DEA and other comparable foreign authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the product candidates meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of product candidates and shutting down of production, any of which could materially adversely affect our business, prospects, financial condition and results of operations. We and any of these third-party suppliers may also be subject to audits by the FDA, the DEA and other comparable foreign authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the product candidates could suffer significant interruptions. We face risks inherent in relying on a limited number of CDMOs, as any disruption, such as a fire, natural hazards or vandalism at the CDMO, or a change in operations as a result of the sale of one of our CDMOs, could significantly interrupt our manufacturing capability. For example, we have engaged Catalent as the exclusive supplier of MM120 ODT. On February 5, 2024, Catalent announced that would be merging with Novo Holdings A/S ("Novo Holdings"). On December 18, 2024, Catalent announced the closing of its merger with Novo Holdings. While we have not experienced any impact on our relationship with Catalent to date, the merger may impact Catalent's management and operations, which could significantly impact our supply chain and require us to find a new CDMO to provide clinical and commercial supplies, if MM120 ODT is approved. We currently do not have disaster recovery facilities available for our product candidates. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial time and capital on our part, which we may not be able to obtain on commercially acceptable terms or at all, and we would likely experience months of manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we may be unable to satisfy manufacturing needs on a timely basis or at all. In addition, operating any new facilities may be more expensive than operating our current facility, and business interruption insurance may not adequately compensate us for any losses that may occur, in which case we

would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have a material adverse effect on our business, including placing our financial stability at risk.

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, academic collaborators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic collaborators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the national competent authorities of the EU Member States, the MHRA and comparable foreign regulatory authorities for all of our product candidates in clinical development.

Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators, academic collaborators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA 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 comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure, or the failure of our third-party contractors and CROs, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Further, these investigators, academic collaborators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators, academic collaborators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. In addition, investigators, academic collaborators and CROs may have difficulty staffing, undergo changes in priorities or become financially distressed or form relationships with other entities, some of which may be our competitors, any of which materially adversely affect our business.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize in or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs, academic collaborators or investigators on commercially reasonable terms or at all. If CROs, academic collaborators or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, or 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. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs (or investigators) involves additional cost and requires management time and focus. In addition, delays occur during the natural transition period when a new CRO commences work, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business or financial condition and prospects.

If we decide to establish collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a 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 or comparable foreign regulatory authorities, 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 drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

If and when we seek to enter into collaborations, we may not be able to negotiate 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 a 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 product revenue.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration 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 revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

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

- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may rely on third parties to conduct development, manufacturing, and/or commercialization activities, and except for remedies available to us under our collaboration agreements, we have limited ability to control the conduct of such activities;

- 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;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;

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

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for 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;

- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;

- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and

- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to the Securities Markets and Ownership of our Common Shares

The price of our common shares is volatile.

The trading price of our common shares is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common shares, regardless of our actual operating performance. In addition to the factors discussed in this "Risk factors" section and elsewhere in this Annual Report, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;

- any adverse development or perceived adverse development with respect to product candidates;

- any safety concerns related to the use of our product candidates;

- our ability to obtain sufficient resources for our clinical trials and preclinical studies;

- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common shares by us, our insiders or our other shareholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic; and
- general economic, political, industry and market conditions.

Stock markets in general and our share price in particular have recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies and our company. For example, from January 1, 2024 to December 31, 2024, the closing price of our common shares on Nasdaq ranged from as low as $3.55 to as high as $11.75 and daily trading volume ranged from approximately 202,226 to 38,105,520 shares on Nasdaq. During this time, we have not experienced any material changes in our financial condition or results of operations that would explain such price volatility or trading volume. These broad market fluctuations may adversely affect the trading price of our common shares. In particular, a large proportion of our common shares have been and may continue to be traded by short sellers which has put and may continue to put pressure on the supply and demand for our common shares, further influencing volatility in their market price. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common shares to fluctuate, which may limit or prevent investors from readily selling their common shares and may otherwise negatively affect the liquidity of our common shares.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk factors" section, could have a dramatic and adverse impact on the market price of our common shares.

Our operating results may fluctuate significantly, which would make our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which would make it difficult to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying share price and share price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and research-stage programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our product candidates, which may vary depending on FDA, EMA, EC or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for MM120 ODT, MM402 and any of our other product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with MM120 ODT, MM402 and any of our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of MM120 ODT, MM402 or any of our other product candidates;
- the level of demand for MM120 ODT, MM402 and any of our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with MM120 ODT, MM402 and any of our other product candidates;
- our ability to commercialize MM120 ODT, MM402 and any of our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;

- future accounting pronouncements or changes in our accounting policies; and

- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common shares could decline substantially. Such a share price decline could occur even when we have met any previously publicly stated guidance we may provide.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act);

- 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 this Annual Report and our periodic reports and proxy statements; and

- exemptions from the requirements of holding nonbinding advisory shareholder votes on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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 avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year (1) in which we have more than $1.235 billion in annual revenue; (2) on which we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) following the fifth anniversary of the date of the first sale of common equity securities of the issuer under an effective Securities Act registration statement.

Notwithstanding the above, we are also currently a "smaller reporting company," meaning that we had a public float of less than $700.0 million as of the last business day of our most recent second fiscal quarter and annual revenues of less than $100.0 million during the most recently completed fiscal year. If we are still considered a "smaller reporting company" at such time as we cease to be an "emerging growth company," we will be subject to increased disclosure requirements. However, the disclosure requirements will still be less than they would be if we were not considered either an "emerging growth company" or "smaller reporting company." Specifically, similar to "emerging growth companies," "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Even after we no longer qualify as an "emerging growth company", we could still qualify as a "smaller reporting company," which would allow us to take advantage of

many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common shares less attractive because we may 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.

Information that is published by third parties, including blogs, articles, message boards and social and other media, has in the past and may in the future include statements not attributable to us and may not be reliable or accurate.

We have received, and may continue to receive, media coverage that is published or otherwise disseminated by third parties, including blogs, articles, message boards and social and other media. This includes coverage that is not attributable to statements made by our directors, officers or employees. For example, we are aware of disputes amongst individuals and entities formerly involved with our company, including a lawsuit brought against Stephen Hurst, a former executive and director of the Company, and others. Though we are not party to this litigation, there can be no assurance that our business, reputation, share price or operations will not be negatively impacted by such disputes or any negative publicity surrounding such disputes. You should read carefully, evaluate and rely only on the information contained in our SEC filings in determining whether to purchase our securities. Information provided by third parties may not be reliable or accurate and could materially impact the trading price of our common shares, which could cause losses to your investments.

Our business and operations could be negatively affected if we become subject to any securities litigation or shareholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Shareholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our common shares or other securities or other reasons may in the future cause us to become the target of securities litigation or shareholder activism. For example, a group of our shareholders nominated four director candidates for election to our six-member Board at our 2023 annual general meeting of shareholders, and waged a proxy contest in support of their candidates and in opposition to four of our Board's director nominees. Securities litigation and shareholder activism, including potential proxy contests, could result in substantial costs and divert management's and our Board's attention and resources from our business. Further, a future proxy contest, unsolicited takeover proposal, or other shareholder activism relating to the election of directors or other matters would most likely result in significant legal fees and proxy solicitation expenses and require significant time and attention. Even if not formally launched, the potential of a proxy contest, unsolicited takeover proposal, or other shareholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and shareholder activism.

Actions of activist shareholders against us have been and could be disruptive and costly, may cause uncertainty about the strategic direction of our business, result in litigation, divert management's and our Board's attention and resources, and may have an adverse effect on our business and stock price.

From time to time, we may be subject to proposals by activist shareholders urging us to take certain corporate actions or to nominate certain individuals to our board of directors. For example, a group of our shareholders nominated four director candidates for election to our six-member Board at our 2023 annual general meeting of shareholders, and waged a proxy contest in support of their candidates and in opposition to four of our Board's director nominees. Future activist shareholder matters, including a proxy contest and potential related litigation, could have a material adverse effect on us for the following reasons:

- Such shareholders may attempt to effect changes in our governance and strategic direction or to acquire control over our Board or the Company.

- While we welcome the opinions of all shareholders, responding to proxy contests and related litigation by shareholders has been, and could be, costly and time-consuming, and could disrupt our operations, and divert the attention of our board of directors, management team and other employees away from their regular duties and the pursuit of business opportunities to enhance shareholder value.

- Perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business, instability or lack of continuity, which may cause concern to our existing or potential collaboration partners, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners any of which could adversely affect our business and operating results.

- Perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist shareholder initiatives may harm our ability to attract new investors, and could cause our stock price to experience periods of volatility or stagnation based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Our articles and certain Canadian legislation contain provisions that may have the effect of delaying or preventing certain change in control transactions or shareholder proposals. Any of these provisions may discourage a potential acquirer from proposing or completing a transaction that may have otherwise presented a premium to our shareholders.

Certain provisions of our articles and certain Canadian legislation, together or separately, could discourage or delay certain change in control transactions or shareholder proposals.

Under our articles, we are required to comply with certain advance notice procedures for nomination of candidates for election as directors at shareholders' meetings. These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

The *Investment Canada Act* requires that a non-Canadian must file an application for review with the Minister responsible for the *Investment Canada Act* and obtain approval of the Minister prior to acquiring control of a "Canadian business" within the meaning of the *Investment Canada Act*, where prescribed financial thresholds are exceeded. Furthermore, limitations on the ability to acquire and hold our Common Shares may be imposed by the *Competition Act* (Canada). This legislation permits the Commissioner of Competition (the "Commissioner"), to review any acquisition or establishment, directly or indirectly, including through the acquisition of shares, of control over or of a significant interest in our company. Otherwise, there are no limitations either under the laws of Canada or the Province of British Columbia, or in our articles on the rights of non-Canadians to hold or vote our common shares.

We are governed by the corporate laws in British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws in Delaware, United States.

There are material differences between the BCBCA and the Delaware General Corporation Law (the "DGCL"), including the following: (i) under the BCBCA, significant corporate actions, such as continuances, certain amalgamations, sales, leases or other dispositions of all or substantially all of the undertaking of a company (other than in the ordinary course of business), liquidations, dissolutions and certain arrangements, require the approval of at least two thirds of the votes cast by a company's shareholders, whereas under Delaware law, a majority of the total voting power of outstanding shares entitled to vote on the matter is generally required for sch matters; (ii) under the BCBCA shareholders holding at least 1/20 of our issued and outstanding common shares can requisition a general meeting at which any matters that can be voted on at our annual meeting can be considered, whereas the DGCL does not give this right; (iii) our articles require two-thirds majority vote by shareholders to pass a resolution for one or more directors to be removed, whereas DGCL only requires the affirmative vote of a majority of the shareholders; however, many public company charters limit removal of directors to a removal for cause; and (iv) our articles may be amended by resolution of our directors to alter our authorized share structure, including to (a) consolidate or subdivide any of our shares and (b) alter the identifying name of any of our shares, whereas under DGCL, a majority vote by shareholders is generally required to amend a corporation's certificate of incorporation and a separate class vote may be required to authorize alterations to a corporation's authorized share structure. We cannot predict if investors will find our common shares less attractive because of these material differences. 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.

If we fail to meet all applicable listing requirements and Nasdaq determines to delist our common shares, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease.

Our common shares are currently listed on Nasdaq. There can be no assurance that we will maintain compliance with the requirements for listing our common shares on Nasdaq. If we fail to meet all applicable listing requirements for the Nasdaq, our common shares could be delisted from the exchange. Delisting could adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the

value and liquidity of our common shares. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Effective April 10, 2024, we voluntarily delisted our common shares from Cboe Canada due to our belief that the trading volume of our common shares on Cboe Canada no longer justified the expense and administrative requirements associated with maintaining the dual listing.

General Risk Factors

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income and taxes may be limited.

Our U.S. federal net operating loss ("NOL") carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. U.S. federal NOLs incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs, is limited to 80% of taxable income. As of December 31, 2024, we had available U.S. federal NOL carryforwards of $165.5 million which can be carried forward indefinitely. We also have available state NOL carryforwards of approximately $20.0 million as of December 31, 2024, which will begin to expire in 2037.

In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986 (as amended) (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-ownership change NOLs and certain other pre-ownership change tax attributes to offset its post-ownership change taxable income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our share ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership of the Company. As a result, our ability to utilize our NOLs and certain other tax attributes could be limited.

There is also a risk that regulatory changes, such as suspensions on the use of NOLs or other unforeseen changes, could cause our existing NOLs to expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. Consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

We will be subject to Canadian and United States tax on our worldwide income.

We will be deemed to be a resident of Canada for Canadian federal income tax purposes by virtue of being incorporated under the laws of a province of Canada. Accordingly, we will be subject to Canadian taxation on our worldwide income, in accordance with the rules in the *Income Tax Act (Canada)* (the "Tax Act") generally applicable to corporations resident in Canada.

Notwithstanding that we will be deemed to be a resident of Canada for Canadian federal income tax purposes, we are treated as a U.S. corporation for U.S. federal income tax purposes, pursuant to Section 7874(b) of the Code, and the U.S. Treasury Regulations promulgated thereunder. Accordingly, we will be subject to a number of significant and complicated U.S. federal income tax consequences as a result of being treated as a U.S. domestic corporation for U.S. federal income tax purposes and will be subject to taxation on our worldwide income both in Canada and the United States, which could have a material adverse effect on our financial condition and results of operations.

Dispositions of common shares may be subject to Canadian tax and will be subject to United States tax, and dividends on common shares will be subject to Canadian and/or United States taxes.

Dispositions of common shares will not be subject to Canadian tax, unless the common shares constitute "taxable Canadian property" (as defined in the Tax Act) of a holder of the common shares that is a non-resident of Canada for purposes of the Tax Act. Such holders whose common shares may constitute taxable Canadian property should consult their own tax advisors. In addition, dispositions of common shares by U.S. Holders (as defined below) will be subject to U.S. tax, and certain dispositions of common shares by Non-U.S. Holders (including if we are treated as a U.S. real property holding corporation ("USRPHC")) will be subject to U.S. tax, as described below.

It is currently not anticipated that we will pay any dividends on the common shares in the foreseeable future. However, to the extent dividends are paid on the common shares, dividends received by shareholders who are residents of Canada for purposes of the Tax Act

(and Non-U.S. Holders for purposes of the Code) will be subject to U.S. withholding tax. Any such dividends may not qualify for a reduced rate of withholding tax under the Canada-United States income tax treaty (the "Treaty"). In addition, a Canadian foreign tax credit or a deduction in respect of such U.S. withholding taxes paid may not be available.

Dividends received by U.S. Holders will not be subject to U.S. withholding tax but will be subject to Canadian withholding tax, subject to any reduction in the rate of withholding under the Treaty. Any such dividends may not qualify for a reduced rate of withholding tax under the Treaty. Dividends paid by us will be characterized as U.S. source income for purposes of the foreign tax credit rules under the Code. Accordingly, U.S. Holders may not be able to claim a credit for any Canadian tax withheld unless, depending on the circumstances, they have other foreign source income that is subject to a low or zero rate of foreign tax.

Dividends received by shareholders that are neither Canadian nor U.S. shareholders will be subject to U.S. withholding tax and will also be subject to Canadian withholding tax. These dividends may not qualify for a reduced rate of U.S. withholding tax under any income tax treaty otherwise applicable to a shareholder of ours, subject to examination of the relevant treaty. These dividends may, however, qualify for a reduced rate of Canadian withholding tax under any income tax treaty otherwise applicable to a shareholder of ours, subject to examination of the relevant treaty.

For purposes hereof, a "U.S. Holder" is a beneficial holder of common shares who or that, for U.S. federal income tax purposes, is:

- an individual who is a United States citizen or resident of the United States;
- a corporation or other entity treated as a corporation for U.S. federal income tax purposes created in, or organized under the laws of, the United States, any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (A) the administration of which is subject to the primary supervision of a U.S. court and which has one or more United States persons (within the meaning of the Code) who have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable U.S. Treasury Regulations to be treated as a U.S. person.

For purposes hereof, a "Non-U.S. Holder" means a beneficial owner of common shares that is not a U.S. Holder (except that, with respect to an entity (or other arrangement taxable as a partnership for U.S. federal income tax purposes), a "Non-U.S. Holder" refers to any partner in such partnership that is not a U.S. Holder as defined above).

As a U.S. domestic corporation for U.S. federal income tax purposes, any gain realized by our Non-U.S. Holders upon a disposition of our common shares generally will not be subject to U.S. federal income tax unless:

- the gain is effectively connected with a trade or business of the Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a United States permanent establishment or fixed base of the Non-U.S. Holder);
- the Non-U.S. Holder is an individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition, and certain other conditions are met; or
- we are or have been classified as a USRPHC for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the Non-U.S. Holder's holding period for such common shares disposed of.

We believe that we presently are not a USRPHC and do not presently anticipate that we will become a USRPHC. However, because this determination is made from time to time and is dependent upon a number of factors, some of which are beyond our control, including the value of our assets, there can be no assurance that we will not become a USRPHC. If we ultimately are determined by the United States Internal Revenue Service ("IRS"), to constitute a USRPHC, our Non-U.S. Holders may be subject to U.S. federal income tax on any gain associated with the disposition of the common shares.

We may incur significant tax liabilities as a result of Section 280E of the Code that could negatively impact the results of our operations.

Section 280E of the Code generally prohibits businesses from deducting or claiming tax credits with respect to expenses paid or incurred in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of Schedule I and II of the CSA) which are prohibited by federal law or the law of any state in which such trade or business is conducted. The application of Section 280E of the Code generally causes such businesses to have an effective tax rate in the United States that is significantly higher than the rate typically applicable to businesses in other industries. The IRS has invoked Section 280E of the Code in tax audits against various businesses in the United States, even when the business activities were permitted under applicable state laws. Although the IRS issued a clarification of Section 280E of the Code that allows the deduction of certain expenses, the scope of such items is interpreted very narrowly and the bulk of operating costs and general administrative costs are not permitted to be deducted In addition, there can be no assurance that courts, in response to challenges of these restrictions by taxpayers, will issue an interpretation of Section 280E of the Code favorable to our businesses.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive information, including personal information (such as health-related information), data related to clinical trials, intellectual property, and trade secrets. We depend on both our own systems, networks, and technology as well as the systems, networks and technology of our collaborative partners, third-party service providers and other business partners to safeguard our data.

Cybersecurity Program

Given the importance of cybersecurity to our business, we maintain a robust cybersecurity program to support both the effectiveness of our systems and our preparedness for information security risks. We also maintain cybersecurity insurance providing coverage for certain costs related to cybersecurity-related incidents that impact our own systems, networks, and technology or the systems, networks and technology of our contractors, consultants, vendors and other business partners. However, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats

We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence. In the event of a cybersecurity incident, we maintain a regularly tested incident response program. Pursuant to the program and its escalation protocols, designated personnel are responsible for assessing the severity of an incident and associated threat, containing the threat, remediating the threat, including recovery of data and access to systems, analyzing reporting obligations associated with the cybersecurity incident, and performing post-incident analysis and program enhancements.

We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. Our information security program is tactically and strategically supplemented via partnerships and engagements with key consultants, vendors, and service providers. We also actively engage with key vendors as part of our continuing efforts to evaluate and enhance the effectiveness of our information security policies and procedures. We use a number of means to assess cyber risks related to our third-party service providers, including vendor questionnaires, vendor audits, vendor qualification, and conducting due diligence in connection with onboarding new vendors and regular vendor reviews. We require third-party service providers with access to sensitive, confidential or proprietary information to implement and maintain robust cybersecurity practices consistent with applicable legal standards and leading industry practices.

Governance

Management Oversight

Our information security program is managed by designated information technology personnel and members of our management team, who are responsible for leading enterprise-wide cybersecurity strategy, policy, standards, architecture, and processes. The controls and processes employed to assess, identify and manage material risks from cybersecurity threats are implemented and overseen by our Information Technology team, consisting of a Vice President of Information Technology, Director of Information Technology and external consultants. Our Information Technology team leverages over 20 years of experience in pharmaceutical and biotechnology information technology, security, and management. Our Information Technology team is responsible for the day-to-day management of the cybersecurity program, including the prevention, detection, investigation, response to, and recovery from cybersecurity threats and incidents, and are regularly engaged to help ensure the cybersecurity program functions effectively in the face of evolving cybersecurity threats. Our Information Technology team provides periodic reports to our senior management as appropriate and informs senior management on an ad hoc basis of significant cybersecurity incidents.

Board Oversight

Our Board has delegated overall responsibility for risk oversight, including cybersecurity risk matters, to our Audit Committee. Our senior management provides periodic reports to our Audit Committee and our Board. These reports include updates on our cyber risks and threats, the status of projects to strengthen our information security systems, assessments of the information security program, and

the emerging threat landscape. In addition, our information security program is regularly evaluated by external experts with the results of those reviews reported to senior management and our Board. The Audit Committee is also promptly apprised of more significant cybersecurity incidents and in the aggregate for less significant incidents.

Cybersecurity Risks

While we maintain a robust cybersecurity program, the techniques used to infiltrate information technology systems continue to evolve. Accordingly, we may not be able to timely detect threats or anticipate and implement adequate security measures. For additional information, see "Item 1A—Risk Factors—If our information technology systems or data, or those of third parties upon which we rely, are of were compromised, we could experience adverse consequences resulting from such compromise, including regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences."

As of December 31, 2024, we have not experienced any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents or threats, that have materially affected our business strategy, results of operations or financial condition in the last year or are reasonably likely to have such a material effect.

Item 2. Properties.

Our U.S. corporate address is located at One World Trade Center Suite 8500, New York, New York 10007, where we lease office space as well as shared use of office services and facilities. The term of the lease automatically renews every six months.

We lease additional office space at 4505 Emperor Boulevard, Durham, North Carolina, 27703. The term of the lease commenced in April 2022 and expires in June 2025.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of our business. We are not currently a party to any material litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Our Common Shares

Our common shares are publicly traded on the Nasdaq Global Select Market under the symbol "MNMD".

Holders of Record

As of December 31, 2024, there were approximately 78 shareholders of record of our common shares. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have not declared or paid any cash dividends on our share capital since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our Board after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements and contractual restrictions of then-existing debt instruments, and other factors that our board of directors deems relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer

None.

Item 6. Reserved.

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

The following discussion should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report. This Annual Report, including the following section, contains forward-looking statements. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Item 1A "Risk Factors" in this Annual Report. See also "Special Note Regarding Forward-Looking Statements." We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Annual Report, except as required by law.

Our U.S. GAAP accounting policies are referred to in Note 2 of the Consolidated Financial Statements. All amounts are in United States dollars, unless otherwise indicated.

Overview

We are a late-stage clinical biopharmaceutical company developing novel product candidates to treat brain health disorders. Our mission is to be the global leader in the development and delivery of treatments for brain health disorders that unlock new opportunities to improve patient outcomes. We are developing a pipeline of innovative product candidates targeting neurotransmitter pathways that play key roles in brain health disorders. This specifically includes pharmaceutically optimized product candidates derived from the psychedelic and empathogen drug classes including MM120 and MM402, our lead product candidates.

Our lead product candidate, MM120, is a proprietary, pharmaceutically optimized form of lysergide D-tartrate that we are developing for the treatment of generalized anxiety disorder and major depressive disorder ("MDD"). In December 2023, we announced positive topline results from our Phase 2b clinical trial of MM120 for the treatment of GAD. The trial met its primary endpoint, with MM120 demonstrating statistically significant and clinically meaningful dose-dependent improvements on the Hamilton Anxiety Rating Scale ("HAM-A") compared to placebo at Week 4. In March 2024, we announced that the U.S. Food and Drug Administration ("FDA") granted breakthrough designation to our MM120 program for the treatment of GAD. We also announced in March 2024 that our Phase 2b clinical trial of MM120 in GAD met its key secondary endpoint, and 12-week topline data demonstrated clinically and statistically significant durability of activity observed through Week 12.

On June 20, 2024, we announced the completion of our End-of-Phase 2 meeting with the FDA, supporting the advancement of MM120 into pivotal trials for the treatment of adults with GAD. Our Phase 3 clinical program for MM120 orally disintegrating tablet ("ODT") is expected to consist of two clinical trials: the Voyage study (MM120-300) and the Panorama study (MM120-301). Both trials are comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel-group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Voyage is anticipated to enroll approximately 200 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo) and Panorama is anticipated to enroll approximately 250 participants (randomized 2:1:2 to receive MM120 ODT 100 µg, MM120 ODT 50 µg or placebo). We expect both trials will utilize an adaptive trial design with a blinded interim sample size re-estimation, allowing for an increase in sample size by up to 50% in each trial in the case of certain parameters. The primary endpoint for each trial is the change from baseline in HAM-A score at Week 12 between MM120 ODT 100 µg and placebo. On December 16, 2024, we announced the initiation of Voyage, with an anticipated topline readout (Part A results) in the first half of 2026. On January 30, 2025, we announced the initiation of Panorama, with an anticipated topline readout (Part A results) in the second half of 2026. Both trials are subject to ongoing regulatory review and discussions, which could result in changes to trial design, including of the Phase 3 clinical trials.

In addition to our Phase 3 clinical program for GAD, we are developing MM120 ODT for the treatment of MDD. In the first quarter of 2024, we held a pre-IND meeting with FDA to discuss the initiation of our Phase 3 clinical program for MM120 ODT in MDD and the trial design for our planned Emerge study (MM120-310), which like our pivotal trials in GAD, we anticipate will be comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Emerge is anticipated to enroll at least 140 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo). The primary endpoint is the change from baseline in Montgomery Åsberg Depression Rating Scale ("MADRS") score at Week 6 between MM120 ODT 100 µg and placebo. We expect to initiate Emerge in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026. We expect to

conduct a second Phase 3 pivotal trial in MDD, with the trial design and timing to be informed by the progress from Emerge and additional regulatory discussions.

Our second lead product candidate, MM402, also referred to as R(-)-MDMA, is our proprietary form of the R-enantiomer of 3,4-methylenedioxymethamphetamine ("MDMA"), which we are developing for the treatment of autism spectrum disorder ("ASD"). MDMA is a synthetic molecule that is often referred to as an empathogen because it is reported to increase feelings of connectedness and compassion. Preclinical studies of R(-)-MDMA demonstrated its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggests that it has the potential to exhibit less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer. In October 2024, we completed our first clinical trial of MM402, a single-ascending dose trial in adult healthy volunteers. The data from this Phase 1 clinical trial helped to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM402. We expect to initiate further trials of MM402 for the treatment of ASD, with the exact timing and scope of such trials to be determined.

Beyond our clinical stage product candidates, we are exploring additional programs, including through external collaborations, which we seek to expand our drug development pipeline and broaden the potential applications of our lead product candidates. These research and development programs include non-clinical, pre-clinical and human clinical trials of current and new product candidates and research compounds with our collaborators.

Our business is premised on a growing body of research supporting the use of novel psychoactive compounds to treat a myriad of brain health disorders. For all product candidates, we intend to proceed through research and development, and with marketing of the product candidates that may ultimately be approved pursuant to the regulations of the FDA and the regulations in other jurisdictions. This entails, among other things, conducting clinical trials with research scientists, using internal and external clinical drug development teams, producing and supplying product candidates according to current Good Manufacturing Practices ("cGMP"), and conducting all trials and development in accordance with the regulations of the FDA, and other regulations in other jurisdictions.

We were incorporated under the laws of the Province of British Columbia in 2010. Our wholly-owned subsidiary, Mind Medicine, Inc. ("MindMed US"), was incorporated in Delaware in 2019. Prior to February 27, 2020, our operations were conducted through MindMed US.

Since inception, we have incurred losses while advancing the research and development of our products and processes. Our net losses were $108.7 million for the year ended December 31, 2024, and $95.7 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $398.9 million and cash and cash equivalents of $273.7 million.

Components of Operating Results

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses. Research and development expenses consist primarily of direct and indirect costs incurred for the development of our product candidates.

External expenses include:

- payments to third parties in connection with the clinical development of our product candidates, including licensing fees and fees to contract research organizations and consultants;
- the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations and consultants;
- payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and sponsored research arrangements with third parties; and
- allocated operational expenses, which include direct or allocated expenses for information technologies and human resources.

We may also incur in-process research and development expenses as we acquire or in-license assets from other parties. Technology acquisitions are expensed or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. Acquired in-process research and development costs that have no alternative future use are immediately expensed.

Internal expenses include employee-related costs such as salaries, related benefits and non-cash stock-based compensation expense for employees engaged in research and development functions.

We expect our research and development expenses to increase for the foreseeable future as we continue the clinical development of our product candidates and other preclinical programs in GAD and MDD and other potential or future indications, including initiating additional and larger clinical trials.

We expense research and development costs in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external costs by program, clinical or preclinical. We do not track internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

General and Administrative

General and administrative expenses consist primarily of compensation costs, including stock-based compensation, for executive management and administrative employees, including finance and accounting, legal, human resources and other administrative functions, professional services fees, advisory and professional service fees in connection with financing transactions, insurance expenses, costs to support our commercialization efforts and allocated expenses.

We expect our general and administrative expenses to increase for the foreseeable future as we continue to advance our research and development programs, grow our business and, if any of our product candidates receive marketing approval, commence commercialization activities.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following tables summarize our results of operations for the periods presented (in thousands):

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023	$ Change	% Change
Operating expenses:				
Research and development	$ 65,297	$ 52,124	$ 13,173	25%
General and administrative	38,619	41,742	(3,123)	-7%
Total operating expenses	103,916	93,866	10,050	11%
Loss from operations	(103,916)	(93,866)	(10,050)	11%
Other income/(expense):				
Interest income	11,558	5,584	5,974	107%
Interest expense	(2,283)	(920)	(1,363)	148%
Foreign exchange (loss)/gain, net	(638)	157	(795)	*
Change in fair value of 2022 USD Financing Warrants	(15,941)	(6,636)	(9,305)	140%
Gain on extinguishment of contribution payable	2,541	—	2,541	100%
Other expense	—	(51)	51	-100%
Total other expense, net	(4,763)	(1,866)	(2,897)	155%
Net loss	(108,679)	(95,732)	(12,947)	14%
Other comprehensive loss:				
Gain/(loss) on foreign currency translation	476	(284)	760	-268%
Comprehensive loss	$ (108,203)	$ (96,016)	$ (12,187)	13%

** Represents a change greater than 300%*

Operating Expenses

Research and Development (in thousands):

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023	$ Change	% Change
External Costs				
MM120 program	$ 34,964	$ 23,516	$ 11,448	49%
MM402 program	3,975	1,904	2,071	109%
Preclinical and other programs	2,845	5,858	(3,013)	-51%
Total external costs	41,784	31,278	10,506	34%
Internal Costs	23,513	20,846	2,667	13%
Total research and development expenses	$ 65,297	$ 52,124	$ 13,173	25%

Research and development expenses increased by $13.2 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to an increase of $11.4 million in expenses related to our MM120 program supporting the advancement into pivotal trials for the treatment of adults with GAD. The MM120 program completed a phase 2b trial in the first half of 2024, and has incurred increased expenses in relation to the initiation of phase 3 trials. Additionally, there was an increase of $2.1 million in expenses related to our MM402 program driven by progress in phase 1 studies, and an increase of $2.7 million in internal personnel costs as a result of increasing research and development capacities, partially offset by a decrease of $3.0 million in expenses related to preclinical activities.

General and Administrative

General and administrative expenses decreased by $3.1 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was primarily attributable to decreased professional services fees and expenses during the year ended December 31, 2024, partially offset by increased stock-based compensation expense and pre-commercialization activities during the year ended December 31, 2024.

Other Income (Expense)

Interest Income

Interest income increased by $6.0 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. This was primarily due to interest earned on our cash and cash equivalents as a result of increased balances held in cash and cash equivalents during the year ended December 31, 2024.

Interest Expense

Interest expense increased by $1.4 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. This was primarily due to interest expense related to our credit facility entered into on August 11, 2023.

Foreign Exchange (Loss)/Gain, Net

Foreign exchange loss increased by $0.8 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, the increase was primarily due to unfavorable changes in foreign exchange rates during the year ended December 31, 2024.

Change in fair value of 2022 USD Financing Warrants

Revaluation loss on the 2022 USD Financing Warrants liability was $15.9 million and $6.6 million for the years ended December 31, 2024 and 2023, respectively. Change in fair value of 2022 USD Financing Warrants consists of revaluation gains and losses attributed to the change in the fair value of our 2022 USD Financing Warrants that were issued as part of our public equity offering which closed on September 30, 2022.

Gain on extinguishment of contribution payable

Gain on extinguishment of contribution payable was $2.5 million for the year ended December 31, 2024. In June 2024, we made a lump sum payment of $0.3 million in full satisfaction of our remaining obligations of the contribution payable liability. As a result, both parties were subsequently released from any further commitments from the agreement. The difference between the fair value of the lump sum payment of $0.3 million, and the carrying value of the contribution payable prior to the settlement of $2.8 million, resulted in the gain on extinguishment of $2.5 million.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have financed our operations primarily from the issuance of equity and our Loan Agreement (as defined below). Our primary capital needs are for funds to support our scientific research and development activities including staffing, manufacturing, preclinical studies, clinical trials, administrative costs and for working capital.

We have experienced operating losses and cash outflows from operations since inception and will require ongoing financing in order to continue our research and development activities. We have not earned any revenue or reached successful commercialization of our product candidates. Our future operations are dependent upon our ability to finance our cash requirements, which will allow us to continue our research and development activities and the commercialization of our product candidates, if approved. There can be no assurance that we will be successful in continuing to finance our operations.

Our cash and cash equivalents and our working capital at December 31, 2024 was $273.7 million and $242.8 million, respectively. We believe that our cash and cash equivalents as of December 31, 2024 will be sufficient to fund our operations into 2027. Based on our current operating plan and anticipated R&D milestones, we expect our cash runway to extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD.

On August 11, 2023 (the "Closing Date"), we and certain of our subsidiaries party thereto, as co-borrowers (together with us, the "Borrowers") entered into a Loan and Security Agreement (the "Loan Agreement") with K2 HealthVentures LLC ("K2HV"), as administrative agent and Canadian collateral agent for lenders thereunder (K2HV, and any other lender from time to time, the "Lenders"), and Ankura Trust Company, LLC, as collateral trustee for the Lenders. The Loan Agreement provides for up to an aggregate principal amount of $50.0 million in term loans ("Term Loans") consisting of a first tranche term loan of $15.0 million funded on the Closing Date, subsequent tranches of term loans totaling $20.0 million to be funded upon the achievement of certain time-based, clinical and regulatory milestones, and an additional tranche term loan of up to $15.0 million upon our request, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders. The second milestone-based tranche of $10.0 million was funded in the second quarter of 2024.

On March 7, 2024, we entered into an underwriting agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., as representatives of the underwriters named therein, in connection with the issuance and sale by us in an underwritten offering (the "March Offering") of 16,666,667 of our common shares at an offering price of $6.00 per share, less underwriting discounts and commissions.

The net proceeds from the March Offering were approximately $93.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

Also on March 7, 2024, we entered into a securities purchase agreement with certain investors, pursuant to which the Investors agreed to purchase, and we agreed to sell 12,500,000 of our common shares at a price of $6.00 per share, in a private placement transaction (the "Private Placement").

The net proceeds from the Private Placement were approximately $70.1 million, after deducting fees and expenses payable by us.

The March Offering and the Private Placement both closed on March 11, 2024.

On June 28, 2024, we entered into the Sales Agreement with the Agent to create an at-the-market equity program under which we from time to time may offer and sell the ATM Shares (as defined below), through or to the Agent. We filed a prospectus supplement on June 28, 2024 allowing for up to $150.0 million of Common Shares (the "ATM Shares") to be sold under the Sales Agreement.

Subject to the terms and conditions of the Sales Agreement, the Agent will use its commercially reasonable efforts to sell the ATM Shares from time to time, based upon our instructions. The Agent will be entitled to a commission of up to 3.0% of the aggregate gross proceeds from each sale of the ATM Shares effectuated through or to the Agent.

We have no obligation to sell any of the ATM Shares and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement.

On August 9, 2024, we entered into an underwriting agreement with Leerink Partners LLC and Evercore Group L.L.C., as representatives of the several underwriters named therein, in connection with the an offering of (i) our common shares, and (ii) to certain investors, pre-funded warrants to purchase our common shares. The offering price for the common shares was $7.00 per share, less underwriting discounts and commissions (the "August Offering"). The offering price for the pre-funded warrants was $6.999 per pre-funded warrant, which represents the per share public offering price for the common shares less a $0.001 per share exercise price for each such pre-funded warrant.

The net proceeds from the August Offering were approximately $70.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The August Offering closed on August 12, 2024.

Future Funding Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Moreover, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development of and seek regulatory approvals for our product candidates. Further, we are subject to all the risks incident in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Our expenses will increase if, and as, we:

- advance our product candidates through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to discover and develop additional product candidates;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our development, manufacturing and commercialization efforts and our operations as a public company.

We believe that our cash and cash equivalents as of December 31, 2024 will be sufficient to fund our operations into 2027. Based on our current operating plan and anticipated R&D milestones, we expect our cash runway to extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we may seek to raise any necessary additional capital through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties or from grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common shares, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, strategic partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or enter into such agreements or arrangements on favorable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our

product development or future commercialization efforts. We have based our projections of operating capital requirements on our current operating plan, which is based on several assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including building a commercial organization, product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our product candidates.

Cash Flows

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Net cash used in operating activities	$ (79,129)	$ (64,365)
Net cash provided by financing activities	253,196	21,848
Foreign exchange impact on cash	(30)	79
Net increase/(decrease) in cash and cash equivalents	$ 174,037	$ (42,438)

Cash flows used in operating activities

Cash used in operating activities for the year ended December 31, 2024 was $79.1 million, which consisted of a net loss of $108.7 million and a net change of $3.3 million in our net operating assets and liabilities, partially offset by $32.9 million in non-cash charges. The non-cash charges primarily consisted of share-based compensation of $16.9 million, a change in fair value on the 2022 USD Financing Warrants liability of $15.9 million, DDSU expense of $0.8 million, amortization of debt issuance costs of $0.7 million, unrealized foreign exchange of $0.5 million, and amortization of intangible assets of $0.5 million, partially offset by a gain on extinguishment of the contribution payable of $2.5 million.

Cash used in operating activities for the year ended December 31, 2023 was $64.4 million, which consisted of a net loss of $95.7 million, partially offset by $25.1 million in non-cash charges and a net change of $6.2 million in our net operating assets and liabilities. The non-cash charges primarily consisted of a change in fair value on the 2022 USD Financing Warrants liability of $6.6 million, share-based compensation of $15.5 million, and amortization of intangible assets of $3.2 million.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2024 was $253.2 million, which consisted of $175.0 million of gross proceeds from the March Offering and Private Placement, $75.0 million in proceeds from the August Offering, $10.0 million proceeds from our credit facility, $8.3 million of proceeds from the exercise of the 2022 USD Financing Warrants, $1.0 million net proceeds from the 2022 ATM, net of issuance costs, and $0.7 million in proceeds from the exercise of options, partially offset by $11.1 million of issuance costs related to the March Offering and Private Placement, $5.0 million of issuance costs related to the August Offering, $0.5 million payment of deferred financing fees related to the 2024 ATM, $0.1 million of our credit facility issuance costs and $0.1 million of withholding taxes paid on vested RSUs.

Cash provided by financing activities for the year ended December 31, 2023 was $21.8 million, which consisted of proceeds of $15.0 million from our credit facility partially offset by $0.8 million payment of our credit facility issuance costs, $7.5 million of net proceeds from the 2022 ATM, net of issuance costs, and $0.1 million of proceeds from the exercise of the 2022 USD Financing Warrants.

Contractual Obligations and Contingencies

We enter into research, development and license agreements in the ordinary course of business where we receive research services and rights to proprietary technologies. Milestone and royalty payments that may become due under various agreements are dependent on, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which is uncertain.

We periodically enter into research and license agreements with third parties that include indemnification provisions customary in the industry. These indemnities generally require us to compensate the other party for certain damages and costs incurred as a result of claims arising from research and development activities undertaken by us or on our behalf. In some cases, the maximum potential amount of future payments that could be required under these indemnification provisions could be unlimited. These indemnification provisions generally survive termination of the underlying agreement. The nature of the indemnification obligations prevents us from making a reasonable estimate of the maximum potential amount we could be required to pay. Historically, we have not made any indemnification payments under such agreements and no amount has been accrued in our financial statements with respect to these indemnification obligations.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Business Combinations

At the time of acquisition, we determine whether what is acquired meets the definition of a business, in which case if it does, the transaction is considered a business combination, and otherwise it is recorded as an asset acquisition.

For an asset acquisition, the net identifiable assets acquired and liabilities assumed are measured at the fair value of the consideration paid, based on their relative fair values at the acquisition date. Acquisition related costs are included in the consideration paid and capitalized. No goodwill is recorded and no deferred tax asset or liability arising from the assets acquired or liabilities assumed is recognized upon the acquisition of the assets.

Business combinations are accounted for using the acquisition method. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. The excess of the fair value of the consideration transferred, over the fair value of our share of the identifiable net assets acquired is recorded as goodwill.

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the fair value of the net identifiable assets acquired and liabilities assumed.

Acquisition costs are expensed as incurred, unless they qualify to be treated as debt issue costs, or as cost of issuing equity securities. The measurement period is the period from the date of acquisition to the date we obtain complete information about facts and circumstances that existed as of the acquisition date – and is subject to a maximum of one year.

Fair Value Measurements

Certain of our assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on 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, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.

- Level 2 – Observable inputs (other than Level 1 quoted prices), such as 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, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 – Unobservable inputs that are supported by little or no market activity that are significant to determining 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 us 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.

Cash and cash equivalents, prepaid and other current assets, accounts payable, and accrued liabilities are all short-term in nature and, as such, their carrying values approximate fair values.

The 2022 USD Financing Warrants (as defined in Note 8 in the notes to our annual financial statements) are liability classified due to not meeting the criteria for equity treatment under the guidance in ASC 815-40. Accordingly, the 2022 USD Financing Warrants were recognized at fair value upon issuance and are remeasured to fair value at the end of each reporting period. Any change in fair value is recognized in general and administrative expense on the consolidated statements of operations. Issuance costs related to warrants were expensed within general and administrative expense on the consolidated statements of operations.

Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate research and development costs incurred during the period, which impacts the amount of accrued expenses and prepaid balances related to such costs as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. To date, our estimated accruals have not differed materially from actual costs incurred.

Research and development costs are expensed in the periods in which they are incurred. External costs consist primarily of payments to outside consultants, third-party CROs, CDMOs, clinical trial sites and central laboratories in connection with our discovery and preclinical activities, process development, manufacturing and clinical development activities. External costs also include laboratory supplies as well as allocated facilities, depreciation and other expenses. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service

that has been performed at each reporting date. We allocate external costs by program, clinical or preclinical. Internal costs consist primarily of employee-related costs including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions. We do not allocate internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

Share-Based Payments

When equity-settled share payments are awarded to management, employees and consultants, the fair value of the equity instruments at the date of grant is charged to the consolidated statements of operations and comprehensive loss over the vesting period. When the terms and conditions are modified before they vest, any increase in the fair value of the shares, measured immediately before and after the modification, is also charged to the consolidated statements of operations and comprehensive loss.

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period and account for forfeitures as they occur. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model.

This model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

Fair Value of common shares— The fair value of our common shares is determined based upon the closing price of our common shares one day prior to grant.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options.

Expected volatility—Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

Expected term—The expected term represents the period that the stock-based awards are expected to be outstanding. We have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally between 5 to 10 years.

Dividend Yield—We have never paid dividends on our common shares and have no plans to pay dividends on our common shares. Therefore, we used an expected dividend yield of zero.

Recent Accounting Pronouncements

See Note 2—Summary of Significant Accounting Policies to our consolidated financial statements included elsewhere in this Annual Report for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the 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.

We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Mind Medicine (MindMed) Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Mind Medicine (MindMed) Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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/ KPMG LLP

We have served as the Company's auditor since 2022.

San Diego, California
March 6, 2025

Mind Medicine (MindMed) Inc.

Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 273,741	$ 99,704
Prepaid and other current assets	7,879	4,168
Total current assets	281,620	103,872
Goodwill	19,918	19,918
Intangible assets, net	—	527
Other non-current assets	613	224
Total assets	$ 302,151	$ 124,541
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,010	$ 4,136
Accrued expenses	12,829	11,634
2022 USD Financing Warrants	24,010	16,476
Total current liabilities	38,849	32,246
Credit facility, long-term	21,854	14,129
Other liabilities, long-term	—	32
Total liabilities	60,703	46,407
Commitments and contingencies (Note 11)		
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of December 31, 2024 and 2023; 75,100,763 and 41,101,303 issued and outstanding as of December 31, 2024 and 2023, respectively	—	—
Additional paid-in capital	639,508	367,991
Accumulated other comprehensive income	819	343
Accumulated deficit	(398,879)	(290,200)
Total shareholders' equity	241,448	78,134
Total liabilities and shareholders' equity	$ 302,151	$ 124,541

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

Mind Medicine (MindMed) Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Years Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 65,297	$ 52,124
General and administrative	38,619	41,742
Total operating expenses	103,916	93,866
Loss from operations	(103,916)	(93,866)
Other income/(expense):		
Interest income	11,558	5,584
Interest expense	(2,283)	(920)
Foreign exchange (loss)/gain, net	(638)	157
Change in fair value of 2022 USD Financing Warrants	(15,941)	(6,636)
Gain on extinguishment of contribution payable	2,541	—
Other expense	—	(51)
Total other expense, net	(4,763)	(1,866)
Net loss	(108,679)	(95,732)
Other comprehensive loss:		
Gain/(loss) on foreign currency translation	476	(284)
Comprehensive loss	$ (108,203)	$ (96,016)
Net loss per common share, basic and diluted	$ (1.54)	$ (2.44)
Weighted-average common shares, basic and diluted (Note 2)	70,461,067	39,157,420

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

Mind Medicine (MindMed) Inc.

Consolidated Statements of Shareholders' Equity

(in thousands, except share amounts)

	Common Shares		Additional Paid-In Capital	Accumulated OCI	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2022	37,979,136	—	344,758	627	(194,468)	150,917
Issuance of common shares, net of share issuance costs	2,232,113	—	7,823	—	—	7,823
Exercise of 2022 USD Financing Warrants	27,000	—	178	—	—	178
Settlement of restricted share unit awards	849,721	—	—	—	—	—
Stock-based compensation expense	—	—	15,183	—	—	15,183
Exercise of stock options	13,333	—	49	—	—	49
Net loss and comprehensive loss	—	—	—	(284)	(95,732)	(96,016)
Balance, December 31, 2023	41,101,303	—	367,991	343	(290,200)	78,134
Issuance of common shares and warrants, net of share issuance costs	38,624,064	—	234,267	—	—	234,267
Issuance of common shares upon settlement of restricted share unit awards, net of shares withheld for tax	823,361	—	(54)	—	—	(54)
Exchange of common shares for pre-funded warrants	(8,325,000)	—	—	—	—	—
Issuance of common shares upon conversion of loan principal	748,129	—	3,000	—	—	3,000
Exercise of 2022 USD Financing Warrants	1,945,523	—	16,675	—	—	16,675
Stock-based compensation expense	—	—	16,913	—	—	16,913
Exercise of stock options, net of options withheld for tax	183,383	—	716	—	—	716
Net loss and comprehensive loss	—	—	—	476	(108,679)	(108,203)
Balance, December 31, 2024	75,100,763	$ —	$ 639,508	$ 819	$ (398,879)	$ 241,448

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

Mind Medicine (MindMed) Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (108,679)	$ (95,732)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	16,913	15,183
Directors' deferred share units expense	761	311
Amortization of intangible assets	527	3,162
Change in fair value of 2022 USD Financing Warrants	15,941	6,636
Gain on extinguishment of contribution payable	(2,541)	—
Unrealized foreign exchange	506	(363)
Amortization of debt issuance costs	725	101
Other non-cash adjustments	62	56
Changes in operating assets and liabilities:		
Prepaid and other current assets	(4,337)	39
Other noncurrent assets	48	51
Accounts payable	(2,126)	2,025
Accrued expenses	3,103	5,318
Other liabilities, long-term	(32)	(1,152)
Net cash used in operating activities	(79,129)	(64,365)
Cash flows from financing activities		
Proceeds from the August Offering	74,999	—
Payment of issuance costs from the August Offering	(5,030)	—
Proceeds from the March Offering and Private Placement	175,000	—
Payment of issuance costs from the March Offering and Private Placement	(11,060)	—
Proceeds from credit facility	10,000	15,000
Payment of credit facility issuance costs	(128)	(844)
Proceeds from the 2022 At-the-Market net of issuance costs	984	7,529
Payment of deferred financing fees related to 2024 At-the-Market	(499)	—
Proceeds from exercise of 2022 USD Financing Warrants	8,268	114
Proceeds from exercise of options	716	49
Withholding taxes paid on vested restricted share units	(54)	—
Net cash provided by financing activities	253,196	21,848
Effect of exchange rate changes on cash	(30)	79
Net increase/(decrease) in cash and cash equivalents	174,037	(42,438)
Cash and cash equivalents, beginning of year	99,704	142,142
Cash and cash equivalents, end of year	$ 273,741	$ 99,704
Supplemental Cash Flow Information		
Cash paid for interest	$ 2,224	$ 534
Supplemental Noncash Disclosures		
Conversion of 2022 USD Financing Warrants to common shares upon exercise of warrants	$ 8,407	$ 64
Reclass of deferred financing fees related to 2022 At-the-Market to additional paid-in capital	$ 332	$ —
Issuance of common shares upon conversion of loan principal	$ 3,000	$ —
Unpaid issuance costs for credit facility	$ —	$ 128
Proceeds from issuance of common shares under the 2022 At-the-Market in prepaid and other current assets	$ —	$ 294

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

Mind Medicine (MindMed) Inc.

Notes to Consolidated Financial Statements

(In thousands, except share and per share amounts)

1. DESCRIPTION OF THE BUSINESS

Mind Medicine (MindMed) Inc. (the "Company" or "MindMed") is incorporated under the laws of the Province of British Columbia. Its wholly owned subsidiaries, Mind Medicine, Inc. ("MindMed US"), HealthMode, Inc., MindMed Pty Ltd., and MindMed GmbH are incorporated in Delaware, Delaware, Australia and Switzerland respectively. MindMed US was incorporated on May 30, 2019.

MindMed is a clinical stage biopharmaceutical company developing novel product candidates to treat brain health disorders. The Company's mission is to be the global leader in the development and delivery of treatments for brain health disorders that unlock new opportunities to improve patient outcomes. The Company is developing a pipeline of innovative product candidates, with and without acute perceptual effects, targeting neurotransmitter pathways that play key roles in brain health disorders. This specifically includes pharmaceutically optimized product candidates derived from the psychedelic and empathogen drug classes, including MM120 and MM402, the Company's lead product candidates

Liquidity

As of December 31, 2024, the Company had an accumulated deficit of $398.9 million. Through December 31, 2024, the Company's financial support has primarily been provided by proceeds from the issuance of its common shares, no par value per share ("Common Shares"), warrants to purchase Common Shares, and the Company's credit facility.

As the Company continues its expansion, it may seek additional financing and/or strategic investments; however, there can be no assurance that any additional financing or strategic investments will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it will most likely be required to reduce its plans and/or certain discretionary spending, which could have a material adverse effect on the Company's ability to achieve its intended business objectives. The accompanying consolidated financial statements do not include any adjustments that might be necessary if it were unable to continue as a going concern. Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date of the issuance of these consolidated financial statements.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "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 the extended transition period for complying with new or revised accounting standards, and as a result of this election, the consolidated financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board ("FASB") standards' effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of the first sale of its common equity securities under an effective Securities Act of 1933 (the "Securities Act") registration statement or such earlier time that it is no longer an emerging growth company.

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 ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates of the Financial Accounting Standards Board ("FASB").

The preparation of financial statements in conformity with U.S. GAAP requires management to make a number of estimates and assumptions relating to the reporting of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates under different assumptions or conditions.

Intercompany balances and transactions, and any unrealized income and expenses arising from intercompany transactions, are eliminated in preparing the consolidated financial statements. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that there is no evidence of impairment.

To conform with the current year presentation, certain prior year amounts related to directors' deferred share units ("DDSU") expense have been reclassified and separately presented from stock-based compensation on the statement of cash flows.

Foreign Currency

Prior to April 1, 2024, the Company's functional currency was the Canadian dollar ("CAD"). Translation gains and losses from the application of the U.S. dollar ("USD") as the reporting currency during the period that the Canadian dollar was the functional currency were included as part of cumulative currency translation adjustment, which is reported as a component of shareholders' equity as accumulated other comprehensive income.

Following the Company's voluntary delisting from Cboe Canada effective April 10, 2024, the Company reassessed its functional currency and determined that, as of April 1, 2024, its functional currency had changed from the CAD to the USD. The Company's analysis included various factors, including: the Company's cash flows and expenses denominated primarily in USD, and the primary market for the Company's Common Shares trading in USD. The change in functional currency was accounted for prospectively from April 1, 2024, and the consolidated financial statements prior to and including the period ended December 31, 2023 were not restated for the change in functional currency.

For periods commencing April 1, 2024, monetary assets and liabilities denominated in currencies other than USD are remeasured at period-end using the period-end exchange rate. 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 April 1, 2024, are translated at the approximate exchange rate prevailing at the date of the transaction. Income and expense accounts are translated at the average rates in effect during the fiscal year. Foreign exchange gains and losses are included in the consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. 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 reflected in these consolidated financial statements include, but are not limited to, the valuation, accrual for research and development costs, and the fair value of share-based awards and warrants. Actual results could differ from those estimates, and such differences could be material to the consolidated balance sheets and statements of operations and comprehensive loss.

Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, views the Company's operations and manages its business as a single operating segment, which is the research and development of the Company's neuro-pharmaceutical drug development platform. All long-lived assets are located in the United States. The Company does not currently generate any revenue.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk primarily consist of cash and cash equivalents. As of December 31, 2024, the Company's cash equivalents primarily includes a U.S. government money market fund at a high-credit quality financial institution which invests in highly liquid securities that are issued or guaranteed by the U.S. government or by U.S. government agencies and instrumentalities. The Company's cash is deposited in checking accounts at high-credit quality financial institutions, which at times, may exceed federally insured limits. Management believes that these financial institutions are financially sound, and, accordingly, minimal credit risk exists with respect to these financial institutions. As of December 31, 2024, the Company has not experienced any losses on its cash or cash equivalents.

Business Combinations

The Company evaluates acquisitions to determine whether it is a business combination or an asset acquisition. The Company accounts for business combinations under the acquisition method of accounting. The Company includes the results of operations of acquired businesses in its consolidated financial statements as of the respective dates of acquisition. The purchase price is allocated to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date, with the excess recorded to goodwill.

The determination of fair value requires considerable judgment and is sensitive to changes in the underlying assumptions. The Company's estimates are preliminary and subject to adjustment, which may result in material changes to the final valuation. During the measurement period, which will not exceed one year from closing, the Company may continue to obtain information to assist in finalizing the acquisition date fair values. Any qualifying changes to the preliminary estimates will be recorded as adjustments to the respective assets and liabilities, with any residual amounts allocated to goodwill. Acquisition costs are expensed as incurred, unless they qualify to be treated as debt issue costs, or as cost of issuing equity securities.

Asset acquisitions are accounted for using a cost accumulation model, with the cost of the acquisition allocated to the acquired assets based on their relative fair values. Goodwill is not recognized in an asset acquisition.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of net tangible and identifiable intangible assets acquired in business combinations. The recognition of goodwill represents the strategic and synergistic benefits the Company expects to realize from acquisitions.

Goodwill is not amortized to earnings, rather, assessed for impairment annually during the fourth quarter for its single reporting unit. The Company also performs an assessment at other times if events or changes in circumstances indicate the carrying value of the assets may not be recoverable. When impairment indicators are identified, the Company compares the reporting unit's fair value to its carrying amount, including goodwill. An impairment loss is recognized as the difference, if any, between the reporting unit's carrying amount and its fair value, to the extent the difference does not exceed the total amount of goodwill allocated to the reporting unit.

In conducting the annual impairment test, the Company first reviews qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If factors indicate that the fair value of the reporting unit is less than its carrying amount, a quantitative assessment is performed and the fair value of the reporting unit is determined by analyzing the total fair value of equity compared to the carrying value of the reporting unit. If the carrying value of the reporting unit continues to exceed its fair value, the implied fair value of the reporting unit's goodwill is calculated and an impairment loss equal to the excess is recorded. No impairment charges have been recorded during the years ended December 31, 2024 and 2023.

Intangible Assets

The Company's finite-lived intangible assets consist of acquired developed technology and are amortized on a straight-line basis, which is aligned to the economic benefit of the asset, over their estimated useful life of three years.

Intangible assets or asset groups are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be fully recoverable. Upon occurrence, recoverability is measured by comparing the sum of the undiscounted expected future cash flows the asset or asset group is expected to generate to its carrying amount. If the carrying amount of the asset exceeds its undiscounted expected future cash flows, an impairment loss is recognized in the amount of the excess of the carrying amount over the fair value of the asset. Any write-downs are treated as permanent reductions in the carrying amount of the respective asset. There was no impairment of intangible assets recorded during the years ended December 31, 2024 and 2023.

Warrants

CAD Financing Warrants and CAD Compensation Warrants

Between 2020 through 2021, in conjunction with equity offerings, the Company issued units at varying prices per unit in CAD, with each unit comprised of one Common Share and one-half of one Common Share financing warrant (each whole warrant, a "CAD Financing Warrant"). The Company also issued compensation warrants to its underwriters (the "CAD Compensation Warrants"). CAD Financing Warrants and CAD Compensation Warrants were classified as equity and recorded at fair value at the time of issuance. All CAD Financing Warrants and the CAD Compensation Warrants expired as of March 9, 2024.

2022 USD Financing Warrants

The 2022 USD Financing Warrants (as defined below in Note 8) are liability classified due to not meeting the criteria for equity treatment under the guidance in ASC 815-40. Accordingly, the 2022 USD Financing Warrants were recognized at fair value upon issuance and are remeasured to fair value at the end of each reporting period. Any change in fair value is recognized on the consolidated statements of operations.

Pre-Funded Warrants

The Pre-Funded Warrants (as defined in Note 7) issued on August 9, 2024, are equity classified due to meeting the indexation and equity classification criterion in ASC 815-40. Therefore, the fair value of the Pre-Funded Warrants was determined upon issuance based on the proceeds received for the Pre-Funded Warrants, and the Pre-Funded Warrants will not be remeasured.

Cash and Cash Equivalents

The Company considers all investments with an original maturity date at the time of purchase of three months or less to be cash and cash equivalents. As of December 31, 2024, the Company's cash equivalents consisted of U.S. government money market funds at a high-credit quality and federally insured financial institution. The Company's accounts, at times, may exceed federally insured limits. The Company had cash equivalents of $271.5 million as of December 31, 2024, and $96.7 million as of December 31, 2023.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on 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, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs (other than Level 1 quoted prices), such as 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, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity that are significant to determining 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.

Cash and cash equivalents, other current assets, accounts payable and accrued expenses are all short-term in nature and, as such, their carrying values approximate fair values.

The Company's credit facility bears variable interest rates, and the carrying amount of the Company's credit facility approximates fair value because interest rates approximate the current rates available to the Company.

Research and Development

Research and development expenses include all direct and indirect operating expenses supporting the products and processes in development, including payroll and benefits, which includes stock-based compensation, for research and development employees, consulting expenses, licensing fees, manufacturing costs to produce clinical trial materials, clinical research costs, and data and study acquisition costs. The Company recognizes the benefit of refundable research and development tax credits as a reduction of research and development costs when received or there is reasonable assurance that the amount claimed will be recovered. The costs incurred in establishing and maintaining patents are expensed as incurred.

Substantial portions of the Company's pre-clinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations ("CROs") and other vendors. These vendors generally bill monthly for services performed, or bill based upon milestone achievement. The Company accrues expenses based upon estimated percentage of 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. 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.

Intellectual property acquired separately for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) are expensed in research and development costs at the time the costs are incurred.

General and Administrative

General and administrative expenses consist primarily of compensation costs, including stock-based compensation, for executive management and administrative employees, including finance and accounting, legal, human resources and other administrative functions, professional services fees, advisory and professional service fees in connection with financing transactions, insurance expenses and allocated expenses. During the year ended December 31, 2023, the Company also incurred additional costs related to public relations, printing and professional services fees in connection with the proxy contest in connection with our 2023 annual general meeting of shareholders. Similar costs were not incurred during the year ended December 31, 2024.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the consolidated statements of operations in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. To date, there have been no interest charges or penalties related to unrecognized tax benefits.

As a result of incurring scientific research and development expenditures, management anticipates that there will be non-refundable tax credits receivable following the completion of normal audit processes by tax authorities. Investment tax credits are recorded at the earlier of when received or when there is reasonable assurance that the amounts claimed will be recovered. Upon recognition, amounts will be recorded as a reduction of research and development expenditures.

Net Loss Per Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of Common Shares outstanding during each period. Diluted net loss per share of Common Shares includes the effect, if any, from the potential exercise or conversion of securities such as share options and warrants, which would result in the issuance of incremental shares of common shares. For diluted net loss per share, the weighted-average number of common shares is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For all periods presented, basic and diluted net loss per share are the same, as any additional share equivalents would be anti-dilutive.

The Company has not adjusted its weighted average number of Common Shares outstanding in the calculation of diluted loss per share, as the effect of warrants and options is anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share attributable to common shareholders (in thousands, except share and per share amounts). As the exercise price of the Company's pre-funded warrants is $0.001 per share, it was determined to be non-substantive for accounting purposes and the pre-funded warrants were included the denominator of both basic and diluted EPS:

	Years Ended December 31,	
	2024	2023
Numerator:		
Net loss attributable to common shareholders	$ (108,679)	$ (95,732)
Denominator:		
Weighted-average pre-funded warrants used in computing net loss per share attributable to common shareholders, basic and diluted	2,256,373	—
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	68,204,694	39,157,420
Total weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	70,461,067	39,157,420
Net loss per share attributable to common shareholders, basic and diluted	$ (1.54)	$ (2.44)

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Years Ended December 31,	
	2024	2023
2022 USD Financing Warrants	5,086,300	7,031,823
Options issued and outstanding under stock option plan	4,225,032	2,161,734
Restricted Share Units	1,371,266	2,294,056
Conversion Shares	249,377	—
Estimated shares issuable under the Employee Share Purchase Plan	37,370	—
CAD Compensation Warrants	—	107,720
CAD Financing Warrants	—	897,667
Total	10,969,345	12,493,000

Stock-based compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants or restricted share unit ("RSU") grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. The Company recognizes forfeitures as they occur.

The fair value of stock options is estimated using a Black-Scholes-Merton valuation model on the date of grant. The Black-Scholes-Merton option-pricing model requires inputs based on certain highly subjective assumptions. Changes to these assumptions can materially affect the fair value of stock options and ultimately the amount of stock-based compensation expense recognized in the Company's consolidated financial statements. These assumptions include:

Fair Value of Common Shares— The fair value of the Company's Common Shares is determined based upon the closing price of the Company's stock one day prior to grant.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options.

Expected volatility—Due to the Company's limited operating history and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the

equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of the Company's own share price becomes available.

Expected term—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally between 5 to 10 years.

Dividend Yield—The Company has never paid dividends on its Common Shares and has no plans to pay dividends on its Common Shares. Therefore, the Company has used an expected dividend yield of zero.

When the terms and conditions are modified before an award vests, any increase in the fair value of the shares, measured immediately before and after the modification, is also charged to the consolidated statements of operations and comprehensive loss.

The Company also grants-cash settled Directors' Deferred Share Units ("DDSUs") to non-executive directors for compensation. Effective June 8, 2023, the Company amended the definition of "Fair Market Value" under the DDSU Plan to be based upon the volume weighted average trading price of the Company's Common Shares as traded on the Nasdaq Stock Market for the five business days on which Common Shares are traded on Nasdaq immediately preceding the applicable date. This change is only applicable for DDSUs granted subsequent to June 8, 2023. Accordingly, DDSUs granted after June 8, 2023 are denominated in USD. The DDSUs generally vest ratably over twelve months after grant and are settled within 90 days of the date the director ceases service to the Company. The Company recognizes expense on the revaluation of DDSU awards as they vest and records the expense to stock-based compensation expense under general and administrative expense in the consolidated statement of operations and comprehensive loss with a corresponding adjustment related to a DDSU liability recorded to accrued expenses in the consolidated balance sheets.

On April 16, 2024, the Company's Board of Directors approved the Mind Medicine (MindMed) Inc. Employee Share Purchase Plan (the "ESPP"), subject to its approval by the Company's shareholders. As of August 15, 2024, the Company commenced the first offering under the ESPP. The fair value of Common Shares to be issued under the ESPP is estimated using a Black-Scholes-Merton valuation model

Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting* ("ASU 2023-07"). ASU 2023-07 requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within the segment measure of profit or loss. This guidance will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023, and interim reporting periods in fiscal years beginning after December 31, 2024. The Company adopted the guidance in the fiscal year ended December 31, 2024. There was no impact on the Company's reportable segments identified. Required disclosures have been included in Note 13.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 requires annual disclosures of specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold and a disaggregation of income taxes paid, net of refunds. ASU 2023-09 also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. ASU 2023-09 is effective for the annual reporting periods in fiscal years beginning after December 31, 2024. Early adoption is permitted. ASU 2023-09 should be applied prospectively. Retrospective adoption is permitted. The Company is currently assessing the impact this standard will have on the Company's consolidated financial statements.

3. CREDIT FACILITY

On August 11, 2023 (the "Closing Date"), the Company and certain of its subsidiaries party thereto, as co-borrowers (together with the Company, the "Borrowers") entered into a Loan and Security Agreement (the "Loan Agreement") with K2 HealthVentures LLC ("K2HV"), as administrative agent and Canadian collateral agent for lenders thereunder (K2HV, together with any other lender from time to time, the "Lenders"), and Ankura Trust Company, LLC, as collateral trustee for the Lenders. The Loan Agreement provides for up to an aggregate principal amount of $50.0 million in term loans (the "Term Loan") consisting of a first tranche term loan of $15.0

million funded on the Closing Date, subsequent tranches of term loans totaling $20.0 million to be funded upon the achievement of certain time-based, clinical and regulatory milestones, and an additional tranche term loan of up to $15.0 million upon the Company's request, subject to review by the Lenders of certain information from the Company and discretionary approval by the Lenders. On the Closing Date, the Company paid a facility fee of $0.3 million to K2HV. The second milestone-based tranche of $10.0 million was funded in the second quarter of 2024.

The Term Loan matures on August 1, 2027, and the obligations of the Borrowers under the Loan Agreement are secured by substantially all of the assets of the Borrowers, excluding intellectual property.

The Term Loan bears a variable interest rate equal to the greater of (i) 10.95% and (ii) the sum of (a) the prime rate as reported in The Wall Street Journal plus (b) 2.95%. The Company may prepay, at its option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the Term Loan, subject to certain prepayment notice requirements; provided that such prepayment notice may be conditioned upon the effectiveness of a refinancing or any other transaction, in which case such prepayment notice may be revoked by the Company. Principal payments were postponed from March 2025 to March 2026 as the interest only extension event per the Loan Agreement was met. Additionally, the Term Loan contains a final payment fee of 6.95% of the original principal amount borrowed due upon the final maturity date or upon prepayment of the Term Loan. As of December 31, 2024, the Company has accrued $0.5 million in relation to this final payment fee.

The Lenders may elect at any time following the Closing Date and prior to the full repayment of the Term Loan to convert any portion of the principal amount of the term loans then outstanding, up to an aggregate principal amount of $4.0 million, into the Company's Common Shares (the "Conversion Shares"), at a conversion price equal to $4.01 per Conversion Share, subject to certain limitations. The embedded conversion option qualifies for a scope exception from derivative accounting because it is both indexed to the Company's own Common Shares and meets the conditions for equity classification. On November 11, 2024, $3.0 million of principal was converted into 748,129 of the Company's Common Shares. As of December 31, 2024, the Company estimated the fair value of the remaining Conversion Shares to be $1.2 million using the Black-Scholes option pricing model.

The Loan Agreement contains customary representations and warranties and affirmative and negative covenants, including covenants that limit or restrict the Company's ability to, among other things: dispose of assets; make changes to the Company's business, management, ownership or business locations; merge or consolidate; incur additional indebtedness, encumbrances or liens; pay dividends or other distributions or repurchase equity; make investments; and enter into certain transactions with affiliates, in each case subject to certain exceptions. The Company is in compliance with the Loan Agreement as of December 31, 2024.

The Company recorded $2.3 million and $0.7 million in interest expense for the years ended December 31, 2024 and 2023, respectively.

Future expected repayments of principal amount due on the credit facility as of December 31, 2024 are as follows (in thousands):

2025		-
2026		12,999
2027		9,001
Total principal repayments	$	22,000
Unamortized debt issuance costs		(628)
Accrued final payment fee		482
Total credit facility, non-current, net	$	21,854

As of December 31, 2024, the Company estimated the fair value of the credit facility to be $22.2 million, assuming the full remaining $1.0 million of principal is converted into Conversion Shares.

4. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2024 and 2023 (in thousands) and the fair value hierarchy of the valuation techniques utilized. The Company classifies its assets and liabilities as either short- or long-term based on maturity and anticipated realization dates.

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents	$ 271,537	$ —	$ —	$ 271,537
Financial liabilities:				
Directors' Deferred Share Unit Liability	$ 1,148	$ —	$ —	$ 1,148
2022 USD Financing Warrant Liability	$ —	$ —	$ 24,010	$ 24,010
	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents	$ 96,682	$ —	$ —	$ 96,682
Financial liabilities:				
Directors' Deferred Share Unit Liability	$ 387	$ —	$ —	$ 387
2022 USD Financing Warrant Liability	$ —	$ —	$ 16,476	$ 16,476

There were no transfers into or out of Level 1, Level 2, or Level 3 during the years ended December 31, 2024 and 2023.

The Company's cash equivalents includes a U.S. government money market fund which invests in highly liquid securities that are issued or guaranteed by the U.S. government or by U.S. government agencies and instrumentalities, and are measured at fair value in accordance with the fair value hierarchy.

The fair value of the warrant liability is measured at fair value on a recurring basis. The 2022 USD Financing Warrants (as defined below in Note 8) are classified as Level 3 in the fair value hierarchy and are determined using the Black-Scholes-Merton option pricing model using the following assumptions:

	As of December 31, 2024	As of December 31, 2023
Share price	$6.96	$3.66
Expected volatility	90.70%	94.72%
Risk-free rate	4.18%	3.87%
Expected life	2.75 years	3.75 years

5. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

During the year ended December 31, 2024, the Company has made no additions to its outstanding goodwill. During the fourth quarter of 2024, the Company performed its annual goodwill impairment test and determined to perform a quantitative analysis. As a result of the quantitative analysis, no impairment loss was recognized. No impairment charges have been recorded during the years ended December 31, 2024 and 2023.

Intangible assets, net

The following table summarizes the carrying value of the Company's intangible assets (in thousands):

	Useful Lives (in years)	As of December 31, 2024 Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	3	$ 9,485	$ (9,485)	$ —
Total intangible assets, net		$ 9,485	$ (9,485)	$ —

	Useful Lives (in years)	As of December 31, 2023 Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	3	$ 9,485	$ (8,958)	$ 527
Total intangible assets, net		$ 9,485	$ (8,958)	$ 527

As of December 31, 2024, developed technology intangible assets were fully amortized. Amortization expense included in research and development expense was $0.5 million and $3.2 million for the years ended December 31, 2024 and 2023, respectively.

6. ACCRUED EXPENSES

At December 31, 2024 and 2023, accrued expenses consisted of the following (in thousands):

	December 31, 2024	2023
Accrued compensation	$ 6,405	$ 4,526
Accrued clinical and manufacturing costs	5,173	1,884
Professional services	973	2,022
Other accruals	278	361
Contribution payable	—	2,841
Total accrued expenses	$ 12,829	$ 11,634

7. SHAREHOLDERS' EQUITY

Common Shares

The Company is authorized to issue an unlimited number of Common Shares, which have no par value. As of December 31, 2024, the Company had 75,100,763 Common Shares issued and outstanding.

Voting Rights - The holders of Common Shares are entitled to one vote for each Common Share held. All holders of Common Shares are entitled to receive notice of any meeting of shareholders of the Company, and to attend, vote and participate at such meetings, except those meetings at which only holders of a specific class of shares are entitled to vote separately as a class under the Business Corporations Act (British Columbia) (the "BCBCA"). A quorum for the transaction of business at a meeting of shareholders is present if at least two shareholders who, in the aggregate, hold at least 33⅓% of the issued shares entitled to be voted at the meeting are present in person or represented by proxy, irrespective of the number of persons actually present at the meeting. If, within one half hour from the time set for the holding of a meeting of shareholders, a quorum is not present in the case of a shareholder meeting not requisitioned by shareholders, the meeting stands adjourned to the time and place determined by the chair of the meeting or the Board. If, at the adjourned meeting, a quorum is not present within one half hour from the time set for the holding of the meeting, the person or persons present and being, or representing by proxy, one or more shareholders entitled to attend and vote at the meeting constitute a quorum.

At-The-Market Facilities

2022 ATM

On May 4, 2022, the Company filed a shelf registration statement on Form S-3 (the "2022 Registration Statement"), as well as an accompanying prospectus supplement ("Prior ATM Prospectus"). In connection with the filing of the 2022 Registration Statement, the Company also entered into a sales agreement (the "Prior Sales Agreement") with Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc. as sales agents (together, the "Prior Agents"), pursuant to which the Company could issue and sell Common Shares for an aggregate

offering price of up to $100.0 million in accordance with the Prior ATM Prospectus under an at-the-market offering program (the “2022 ATM”). Pursuant to the 2022 ATM, the Company paid the Prior Agents a commission rate equal to 3.0% of the gross proceeds from the sale of any Common Shares. The Company was not obligated to make any sales of its Common Shares under the 2022 ATM. During the year ended December 31, 2024, the Company sold 171,886 Common Shares for net proceeds of $0.7 million under the 2022 ATM. As of March 7, 2024, the Company had raised an aggregate of $40.9 million under the 2022 ATM and had the remaining availability of $59.1 million. On March 7, 2024, the Company announced that it had delivered written notice to the Prior Agents that it was suspending and terminating the 2022 ATM prospectus, dated May 16, 2022. On May 28, 2024, the Company delivered written notice to the Prior Agents that it was terminating the Prior Sales Agreement.

2024 ATM

On June 28, 2024, the Company filed a shelf registration statement on Form S-3 (the “2024 Registration Statement”), as well as an accompanying prospectus supplement (“New ATM Prospectus”). In connection with the filing of the 2024 Registration Statement and the New ATM Prospectus, the Company entered into a sales agreement (the "Sales Agreement") with Leerink Partners LLC (the “Agent”) pursuant to which the Company may issue and sell from time to time Common Shares for an aggregate offering price of up to $150.0 million in accordance with the New ATM Prospectus under an at-the-market offering program (the "2024 ATM"). Pursuant to the 2024 ATM, the Company will pay the Sales Agent a commission rate of up to 3.0% of the gross proceeds from the sale of any Common Shares. The Company is not obligated to make any sales of its Common Shares under the 2024 ATM. The Company has not sold any Common Shares under the 2024 ATM as of December 31, 2024.

The March Offering and Private Placement

On March 7, 2024, the Company entered into an underwriting agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., as representatives of the underwriters named therein, in connection with the issuance and sale by the Company in an underwritten offering (the “March Offering”) of 16,666,667 Common Shares (the “Offering Shares”), at an offering price of $6.00 per Offering Share, less underwriting discounts and commissions.

The net proceeds to the Company from the March Offering were $93.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

Also on March 7, 2024, the Company entered into a securities purchase agreement with certain investors, pursuant to which the investors agreed to purchase, and the Company agreed to sell 12,500,000 Common Shares (the “Private Placement Shares”), at a price of $6.00 per Private Placement Share, in a private placement transaction (the “Private Placement”).

The net proceeds to the Company from the Private Placement were $70.1 million, after deducting fees and expenses payable by the Company.

The Company intends to use the net proceeds from the March Offering and the Private Placement for (i) the research and development of the Company’s product candidates and (ii) working capital and general corporate purposes.

The March Offering and the Private Placement both closed on March 11, 2024.

The August Offering

On August 9, 2024, the Company entered into an underwriting agreement with Leerink Partners LLC and Evercore Group L.L.C., as representatives of the several underwriters named therein, in connection with an underwritten public offering (the “August Offering”) of (i) 9,285,511 Common Shares (the “Shares”), and (ii) to certain investors, pre-funded warrants (the “Pre-Funded Warrants”) to purchase 1,428,775 Common Shares (the "Pre-Funded Warrant Shares"). The offering price for the Shares was $7.00 per share, less underwriting discounts and commissions. The offering price for the Pre-Funded Warrants was $6.999 per Pre-Funded Warrant, which represents the per share public offering price for the Shares less a $0.001 per share exercise price for each such Pre-Funded Warrant.

The net proceeds to the Company from the August Offering were approximately $70.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The August Offering closed on August 12, 2024.

The Company intends to use the net proceeds from the August Offering to fund the research and development of its product candidates and for working capital and general corporate purposes.

The Pre-Funded Warrants are exercisable at any time after the date of issuance. The exercise price and the number of Pre-Funded Warrant Shares are subject to appropriate adjustment in the event of certain share dividends and distributions, share splits, share combinations, reclassifications or similar events affecting the Common Shares as well as upon any distribution of assets, including cash, securities or other property, to the Company's shareholders. The Pre-Funded Warrants will not expire and are exercisable in cash or by means of a cashless exercise. A holder of Pre-Funded Warrants may not exercise such Pre-Funded Warrants if the aggregate number of Common Shares beneficially owned by such holder, together with its affiliates, would exceed more than 4.99% or 9.99% (at the initial election of the holder) of the number of Common Shares outstanding following such exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. A holder of Pre-Funded Warrants may increase or decrease this percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

October Exchange Agreements

October 17, 2024, the Company entered into exchange agreements (the "Exchange Agreements") with Commodore Capital Master LP, Deep Track Biotechnology Master Fund, LTD and certain other investors (collectively, the "Holders") pursuant to which the Holders exchanged an aggregate of 8,325,000 of Common Shares for pre-funded warrants to purchase an aggregate of 8,325,000 Common Shares of the Company with an exercise price of $0.001 per share. Such Common Shares were retired upon exchange. The exchange transactions represented offsetting increases and decreases with APIC that had no overall impact to the Company's financial statements.

Common Shares Reserved for Issuance

A summary of shares reserved for issuance as of December 31, 2024 is summarized below:

	December 31, 2024
Pre-Funded Warrants	9,753,775
2022 USD Financing Warrants	5,086,300
Shares available to grant under incentive plan	4,918,816
Options issued and outstanding	4,225,032
Restricted Share Units issued and outstanding	1,371,266
Shares available to grant under ESPP	712,630
Conversion shares	249,377
Estimated shares issuable under ESPP	37,370
Total shares reserved for issuance	26,354,566

8. WARRANTS

CAD Financing Warrants and CAD Compensation Warrants

Between 2020 through 2021, in conjunction with equity offerings, the Company issued units at varying prices per unit in CAD, with each unit comprised of one Common Share and one-half of one Common Share financing warrant (each whole warrant, a "CAD Financing Warrant"). The Company also issued compensation warrants to its underwriters (the "CAD Compensation Warrants"). CAD Financing Warrants and CAD Compensation Warrants were classified as equity and recorded at fair value at the time of issuance. All CAD Financing Warrants and the CAD Compensation Warrants expired as of March 9, 2024**.**

2022 USD Financing Warrants

On September 30, 2022, the Company closed an underwritten public offering of 7,058,823 Common Shares and accompanying 2022 USD Financing Warrants (each whole warrant, a "2022 USD Financing Warrant") to purchase 7,058,823 Common Shares. Each 2022 USD Financing Warrant is immediately exercisable for one Common Share at an initial exercise price of $4.25 per Common Share, subject to certain adjustments, and will expire on September 30, 2027.

The below table represents the activity associated with the Company's 2022 USD Financing Warrants for the year ended December 31, 2024:

	2022 USD Financing Warrants
Balance at December 31, 2023	7,031,823
Exercised	(1,945,523)
Expired	—
Balance at December 31, 2024	5,086,300

Under the guidance in ASC 815-40, the Company's 2022 USD Financing Warrants do not meet the criteria for equity treatment. Therefore, the Company accounts for the 2022 USD Financing Warrants as liabilities and recognized them at fair value upon issuance and adjusts them to fair value at the end of each reporting period. Any change in fair value is recognized on the consolidated statements of operations and comprehensive loss.

The below table summarizes the activity of the outstanding liability for the 2022 USD Financing Warrants for the year ended December 31, 2024 (in thousands):

	As of December 31, 2024
Balance at December 31, 2023	$ 16,476
Warrant exercise	(8,407)
Change in fair value of the warrant liability	15,941
Balance at December 31, 2024	$ 24,010

9. STOCK-BASED COMPENSATION

Stock Incentive Plans

Effective March 7, 2023, the Company amended the definitions of “Fair Market Value” and “Market Value” under the MindMed Stock Option Plan (the “Stock Option Plan”) and the Performance and Restricted Share Unit Plan (the “RSU Plan”), respectively, to be based upon the closing price of the Company's Common Shares as traded on the Nasdaq Stock Market on the last trading day on which Common Shares traded prior to the day on which an equity award is granted (the “Amendments”). This change is only applicable for equity compensation awards granted subsequent to the Amendments. Accordingly, stock options granted after March 7, 2023 ("USD Options") are denominated in USD, and the grant date fair value of restricted share units granted after March 7, 2023 ("USD RSUs") is denominated in USD. The fair value of both USD Options and USD RSUs is based upon the closing price of the Company's Common Shares as traded on the Nasdaq Stock Market.

As of December 31, 2024, in conjunction with the voluntary Cboe Canada delisting effective as of April 10, 2024, all of the Company's Common Shares are only traded on the Nasdaq Stock Market. All outstanding stock options have their exercise prices denominated in USD based upon the USD value on the day on which the equity award was granted.

Stock Options

On February 27, 2020, the Company adopted the Stock Option Plan to advance the interests of the Company by providing employees, contractors and directors of the Company a performance incentive for continued and improved service with the Company. The Stock Option Plan sets out the framework for determining eligibility as well as the terms of any stock-based compensation granted. The Stock Option Plan was approved by the shareholders as part of the terms of an arrangement agreement (the “Arrangement”) entered into by the Company on October 15, 2019, in connection with the completion of its reverse acquisition, which completed on February 27, 2020. The Company is authorized to issue such number of stock options equal to 15% of the Company’s issued and outstanding Common Shares under the terms of the Stock Option Plan, together with Common Shares that are issuable pursuant to outstanding awards or grants under any other compensation or incentive mechanism involving the issuance or potential issuance of Common Shares, including the RSU Plan and ESPP.

The fair value of options issued has been estimated using the Black-Scholes-Merton option pricing model with the following assumptions:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Share price	$4.98 - $9.40	$2.98 - $3.61
Expected volatility	87.8% - 93.4%	87.2%
Risk-free rate	3.5% - 4.5%	2.8% - 3.9%
Expected life	5.0 - 6.1 years	5.3 - 6.1 years
Expected dividend yield	0%	0%

The following table summarizes the Company's stock option activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2023	2,161,734	$ 18.67	—	$ —
Issued	2,626,980	6.00	—	—
Exercised	(215,978)	4.22	—	—
Forfeited	(300,971)	7.32	—	—
Expired	(46,733)	18.31	—	—
Options outstanding at December 31, 2024	4,225,032	12.35	6.6	$ 4,147,893
Options vested and exercisable at December 31, 2024	1,838,283	18.70	3.9	$ 1,499,022

The weighted average grant date fair value of options granted during the year ended December 31, 2024 was $4.68. The aggregate intrinsic value of options vested during the year ended December 31, 2024 was $7.5 million. The expense recognized related to options during the years ended December 31, 2024 and 2023 was $8.2 million and $6.6 million, respectively.

Restricted Share Units

The Company adopted the RSU Plan to advance the interests of the Company by providing employees, contractors and directors of the Company a performance incentive for continued and improved service with the Company. The RSU Plan sets out the framework for determining eligibility as well as the terms of any stock-based compensation granted. The RSU Plan was approved by the shareholders as part of the Arrangement. The Company is authorized to issue such number of RSUs equal to 15% of the Company's issued and outstanding Common Shares under the terms of the RSU Plan, together with Common Shares that are issuable pursuant to outstanding awards or grants under any other compensation or incentive mechanism involving the issuance or potential issuance of Common Shares, including the Option Plan and ESPP. The fair value has been estimated based on the closing price of the Common Shares on the day prior to the grant.

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at December 31, 2023	2,288,726	$ 7.20
Granted	216,800	7.99
Vested and issued	(823,591)	9.47
Cancelled	(310,669)	5.47
Balance at December 31, 2024	1,371,266	$ 6.35

The fair market value of RSUs vested during the year ended December 31, 2024 was $8.0 million. The expense recognized related to RSUs during the years ended December 31, 2024 and 2023 was $8.7 million and $8.6 million, respectively.

Employee Share Purchase Plan

On April 16, 2024, the Company's Board of Directors approved the Mind Medicine (MindMed) Inc. Employee Share Purchase Plan (the "ESPP"), subject to its approval by the Company's shareholders. On June 10, 2024, the Company's shareholders approved the ESPP at the Company's 2024 Annual General and Special Meeting of Shareholders. A total of 750,000 Common Shares were reserved for future issuance under the ESPP.

As of August 15, 2024, the Company commenced the first offering under the ESPP. The fair value of Common Shares to be issued under the ESPP was estimated using the following assumptions:

	Year Ended December 31, 2024
Expected term	0.5 years
Expected volatility	100.78%
Risk-free rate	5.04%
Weighted average grant date fair value per share	$2.79

Stock-based Compensation Expense

Stock-based compensation expense for all equity arrangements for the years ended December 31, 2024 and 2023 was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 6,126	$ 7,087
General and administrative	10,787	8,096
Total stock-based compensation expense	$ 16,913	$ 15,183

As of December 31, 2024, there was approximately $12.7 million of total unrecognized stock-based compensation expense related to unvested options granted to employees under the Stock Option Plan that is expected to be recognized over a weighted average period of 2.8 years. As of December 31, 2024, there was approximately $7.4 million of total unrecognized stock-based compensation expense related to RSUs granted to employees under the RSU Plan that is expected to be recognized over a weighted average period of 1.9 years. As of December 31, 2024, there was a nominal amount of total unrecognized stock-based compensation expense related to the Common Shares to be issued under the ESPP that is expected to be recognized over a weighted average period of 0.2 years.

Directors' Deferred Share Unit Plan

On April 16, 2021, the Company adopted the MindMed Director's Deferred Share Unit Plan (the "DDSU Plan"). The DDSU Plan sets out a framework to grant nonexecutive directors deferred share units ("DDSUs") which are cash settled awards. Effective June 8, 2023, the Company amended the definition of "Fair Market Value" under the DDSU Plan to be based upon the volume weighted average trading price of the Company's Common Shares as traded on the Nasdaq Stock Market for the five business days on which Common Shares are traded on Nasdaq immediately preceding the applicable date. This change is only applicable for DDSUs granted subsequent to June 8, 2023. Accordingly, DDSUs granted after June 8, 2023 are denominated in USD. The DDSUs generally vest ratably over twelve months after grant and are settled within 90 days of the date the director ceases service to the Company.

	Number of DSUs
Balance at December 31, 2023	199,026
Issued	—
Settled	—
Cancelled	—
Balance at December 31, 2024	199,026

For the year ended December 31, 2024, stock-based compensation expense of $0.8 million was recognized relating to the revaluation of the vested DDSUs, recorded in general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. During the year ended December 31, 2024, the Company did not issue any additional DDSUs. There were 199,026 DDSUs vested as of December 31, 2024. The liability associated with the outstanding vested DDSU's was $1.1 million as of December 31, 2024, and was recorded to accrued expenses in the accompanying consolidated balance sheets.

10. INCOME TAXES

The Components of the loss before income taxes were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Domestic	$ (123,631)	$ (89,536)
Foreign	14,952	(6,196)
Total	$ (108,679)	$ (95,732)

For purposes of reconciling the Company's provision for income taxes at the statutory rate and the Company's provision (benefit) for income taxes at the effective tax rate, a notional of 21% tax rate was applied as follows (in thousands):

	December 31,	
	2024	2023
Income tax at federal statutory rate	$ (22,820)	$ (20,104)
State income tax expense, net of federal tax effect	(1)	331
Nondeductible permanent items	55	51
Executive compensation	952	423
Warrant fair value adjustment	(212)	2,477
Foreign rate differential	3,512	(957)
Adjustment to deferred taxes	(1,641)	783
Nonqualified stock option and performance award windfall upon exercise	1,253	2,002
Change in valuation allowance	18,902	14,994
	$ —	$ —

The difference between the statutory federal income tax rate and the Company's effective tax rate in 2024 and 2023 is primarily attributable to the change in valuation allowance, foreign rate differential, executive compensation, and capitalized research expenses.

The following table provides the effect of temporary differences that created deferred income taxes as of December 31, 2024 and 2023. Deferred tax assets and liabilities represent the future effects on income taxes resulting from temporary differences and carryforwards at the end of the respective periods (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Reserves	$ 868	$ 730
Stock-based compensation	2,652	1,936
Share issuance costs	840	2,139
Net operating loss carryforward	42,466	31,560
Other assets	81	677
Intangible assets	1,164	945
Capitalized R&D	21,821	13,128
Lease liability	8	22
Other	25	—
Valuation allowance	(69,925)	(51,023)
Net deferred income tax assets	—	114
Deferred tax liabilities:		
Right of use asset	—	(20)
Other	—	(94)
Total deferred tax liabilities	—	(114)
Net deferred income tax liability	$ —	$ —

As of December 31, 2024 and 2023, management assessed the realizability of deferred tax assets and evaluated the need for a valuation allowance for deferred tax assets on a jurisdictional basis. This evaluation utilizes the framework contained in ASC 740,

Income Taxes, wherein management analyzes all positive and negative evidence available at the balance sheet date to determine whether all or some portion of the Company's deferred tax assets will not be realized. Under this guidance, a valuation allowance must be established for deferred tax assets when it is more-likely-than-not that the asset will not be realized. In assessing the realization of the Company's deferred tax assets, management considers all available evidence, both positive and negative.

In concluding on the evaluation, management placed significant emphasis on guidance in ASC 740, which states that "a cumulative loss in recent years is a significant piece of negative evidence that is difficult to overcome." Based upon available evidence, it was concluded on a more-likely-than-not basis that all deferred tax assets were not realizable as of December 31, 2024 and 2023. Accordingly, a valuation allowance of $69.9 million has been recorded to offset this deferred tax asset. The valuation allowance increased by $18.9 million for the year ended December 31, 2024.

As of December 31, 2024, the Company has accumulated federal and state net operating loss ("NOL") carryforwards of $165.5 million and $20.0 million, respectively. The federal NOL carryforwards can be carried forward indefinitely, subject to 80% taxable income limitation. The state NOL carryforwards will begin to expire in 2037, unless previously utilized.

As of December 31, 2024 the Company had combined foreign net operating loss carryforwards available to reduce future taxable income of approximately $25.4 million, of which $0.8 million carryforward indefinitely, $20.0 million begin to expire in 2040, and $4.6 million begin to expire in 2028.

Utilization of the Company's net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. Such an annual limitation could result in the expiration or elimination of the net operating loss and tax credit carryforwards before utilization. Management believes that the limitation will not limit utilization of the carryforwards prior to their expiration.

The Company is subject to taxation in the United States, various states, Canada, Australia and Switzerland. The Company has not been notified that it is under audit by the IRS or any state or foreign taxing authorities, however, due to the presence of NOL carryforwards, all of the income tax years remain open for examination in each of these jurisdictions.

Deferred income taxes have not been provided for undistributed earnings of the Company's consolidated foreign subsidiaries because of the Company's intent to reinvest such earnings indefinitely in active foreign operations.

As of December 31, 2024 and 2023 the Company did not have a liability for unrecognized tax benefits.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2024 and 2023, interest and penalties recognized were insignificant.

The Tax Cuts and Jobs Act subjects a U.S. shareholder to tax on GILTI earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740 No. 5. Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred.

11. COMMITMENTS AND CONTINGENCIES

As of December 31, 2024 and 2023, the Company has obligations to make future payments, representing significant research and development contracts and other commitments that are known and committed in the amount of approximately $103.8 million and $28.0 million, respectively. Most of these agreements are cancelable by the Company with notice. These commitments include agreements related to the conduct of the clinical trials, sponsored research, manufacturing and preclinical studies.

The Company enters into research, development and license agreements in the ordinary course of business where the Company receives research services and rights to proprietary technologies. Milestone and royalty payments that may become due under various agreements are dependent on, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which are uncertain.

The Company periodically enters into research and license agreements with third parties that include indemnification provisions customary in the industry. These guarantees generally require the Company to compensate the other party for certain damages and costs incurred as a result of claims arising from research and development activities undertaken by or on behalf of the Company. In some cases, the maximum potential amount of future payments that could be required under these indemnification provisions could be unlimited. These indemnification provisions generally survive termination of the underlying agreement. The nature of the

indemnification obligations prevents the Company from making a reasonable estimate of the maximum potential amount it could be required to pay. Historically, the Company has not made any indemnification payments under such agreements and no amount has been accrued in the consolidated financial statements with respect to these indemnification obligations.

Operating Lease Agreement

During April 2022, the Company entered into a 3-year operating lease for office space located in North Carolina. Total lease payments under the lease amount to approximately $0.2 million and the Company recorded a related right-of-use asset and related lease liability upon lease commencement of approximately $0.2 million. Upon the expiration of the initial term of the lease, the Company has the option to extend the term of the lease for an additional 5-year period. The right-of-use asset is recorded in other non-current assets in the accompanying consolidated balance sheet. The current portion of the lease liability is recorded in accrued expenses and the noncurrent portion is recorded in other liabilities, long-term in the accompanying consolidated balance sheet. The incremental borrowing rate utilized in the determination of the lease liability was 8.0%.

12. EMPLOYEE BENEFIT PLANS

During the year ended December 31, 2023, the Company adopted a 401(k) savings plan for its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of employee contributions, and 50% on the next 2% of employee contributions. The Company contributed $0.5 million and $0.4 million during the years ended December 31, 2024 and 2023, respectively.

13. SEGMENT REPORTING

The Company has one reportable segment relating to the research and development of the Company's neuropharmaceutical drug development platform.

The Company's Chief Operating Decision Maker (the "CODM"), its Chief Executive Officer, reviews the Company's operations, including reviewing budgets and trial related data, and decides how to allocate resources and assess performance. When evaluating the Company's financial performance, the CODM regularly reviews total expenses and total assets and the CODM makes decisions using this information on a consolidated basis. The CODM uses consolidated net income or loss as a measure of profit or loss in allocating resources and assessing segment performance. In addition to the expense categories included within net income presented on the Company's Consolidated Statements of Operations and Comprehensive Loss, see below for additional expense detail that is routinely reviewed by the CODM:

	Year Ended December 31,	
	2024	2023
Research and development:		
Internal expenses	$ 23,513	$ 20,846
External expenses	41,784	31,278
Total	$ 65,297	$ 52,124
General and administrative:		
Internal expenses	$ 18,986	$ 15,467
External expenses	19,633	26,275
Total	$ 38,619	$ 41,742
Loss from operations	$ (103,916)	$ (93,866)
Total other expense, net	$ (4,763)	$ (1,866)
Net loss	$ (108,679)	$ (95,732)

Internal expenses include employee-related costs such as salaries, related benefits, non-cash stock-based compensation expense for employees, and allocated operational expenses. External expenses include services rendered by third party providers for research and development as well as general and administrative activities.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of December 31, 2024, our Chief Executive Officer and Principal Financial Officer carried out an evaluation with the participation of management of 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. Based upon that evaluation, our Chief Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2024.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Management conducted an assessment of our internal control over financial reporting based on the framework established in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting as required by Section 404(c) of the Sarbanes Oxley Act of 2002. Because we qualify as an emerging growth company under the JOBS Act, management's report was not subject to attestation by our independent registered public accounting firm.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Securities Exchange Act of 1934 that occurred during the quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

During the three months ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (in each case, as defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2024, and is incorporated herein by reference.

Item 11. Executive Compensation.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2024, and is incorporated herein by reference.

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2024, and is incorporated herein by reference.

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2024, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is KPMG LLP, San Diego, California, Auditor Firm ID: 185.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2024, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

(1) Financial Statements

The financial statements of Mind Medicine (MindMed) Inc. are filed as part of this Annual Report under Item 8. Financial Statements and Supplementary Data.

(2) Financial Statement Schedules

All other schedules have been omitted because they are not required, not inapplicable, or the required information is included in the financial statements or notes thereto.

(3) Exhibits

Exhibit Number	Description	Form	Exhibit No.	Incorporated by Reference Filing Date	File No.
3.1	Amended and Restated Articles of Mind Medicine (MindMed) Inc., effective as of June 30, 2022.	10-K	3.1	March 9, 2023	001-40360
3.2	Notice of Articles, Incorporated on July 26, 2010, effective as of July 30, 2024.	10-Q	3.2	August 13, 2024	001-40360
4.1*	Description of Capital Stock of Mind Medicine (MindMed) Inc.				
4.2	Form of Mind Medicine (MindMed) Inc. Common Share Certificate.	10-K	4.2	February 28, 2024	001-40360
4.3	Form of Warrant to Purchase Common Shares of Mind Medicine (MINDMED) Inc.	10-K	4.3	March 28, 2022	001-40360
4.4	Form of Warrant Indenture by and between Mind Medicine (MindMed) Inc. and Odyssey Trust Company	10-K	4.6	March 28, 2022	001-40360
4.5	Form of 2022 USD Financing Warrant	8-K	4.1	September 28, 2022	001-40360
4.6	Supplemental Warrant Indenture dated August 26, 2022, by and between Mind Medicine (MindMed) Inc. and Computershare Trust Company of Canada to the Warrant Indenture dated January 7, 2021	10-K	4.10	March 9, 2023	001-40360
4.7	Form of Pre-Funded Warrant	8-K	4.1	August 12, 2024	001-40360
4.8	Form of Pre-Funded Warrant	8-K	4.1	October 17, 2024	001-40360
4.9	Form of Pre-Funded Warrant	8-K	4.3	November 7, 2024	001-40360
10.1#	Form of Director and Officer Indemnity Agreement.	10-K	10.1	March 28, 2022	001-40360
10.2#	Form of Restricted Share Unit Grant Agreement to Performance and Restricted Share Unit Plan.	10-K	10.4	March 28, 2022	001-40360
10.3#	Executive Employment Agreement dated as of November 9, 2022 between Mind Medicine (MindMed) Inc. and Robert Barrow	10-Q	10.1	November 10, 2022	001-40360
10.4#	Executive Employment Agreement dated as of November 9, 2022 between Mind Medicine (MindMed) Inc. and Dr. Daniel Karlin	10-Q	10.2	November 10, 2022	001-40360

10.5#	Executive Employment Agreement dated as of November 9, 2022 between Mind Medicine (MindMed) Inc. and Carrie F. Liao	10-Q	10.5	November 10, 2022	001-40360
10.6	Escrow Agreement among Mind Medicine (MindMed) Inc. and Odyssey Trust Company and Each of the Undersigned Security Holders, dated as of February 26, 2021.	10-K	10.10	March 28, 2022	001-40360
10.7	Supplemental Warrant Agreement by and between Mind Medicine (MindMed) Inc., Computershare Trust Company of Canada and Odyssey Trust Company dated as of March 14, 2022.	10-K	10.11	March 28, 2022	001-40360
10.8#	Mind Medicine (MindMed) Inc. Stock Option Plan (as amended and restated on March 7, 2023).	10-K	10.15	March 9, 2023	001-40360
10.9#	Mind Medicine (MindMed) Inc. Performance and Restricted Share Unit Plan (as amended and restated on March 7, 2023).	10-K	10.16	March 9, 2023	001-40360
10.10#	Form of Option Agreement to Mind Medicine (MindMed) Inc. Stock Option Plan.	10-K	10.17	March 9, 2023	001-40360
10.11+	K2 HealthVentures LLC Loan and Security Agreement	8-K	10.1	August 14, 2023	001-40360
10.12#	Executive Employment Agreement, dated as of April 13, 2023 between Mind Medicine (Minded) Inc. and Mark R. Sullivan	10-Q	10.1	May 4, 2023	001-40360
10.13#	Non-Employee Director Compensation Policy, amended as of June 8, 2023	10-Q	10.2	August 3, 2023	001-40360
10.14	Directors' Deferred Share Unit Plan, amended as of June 8, 2023	10-Q	10.3	August 3, 2023	001-40360
10.15	Exchange Agreement, dated as of October 17, 2024, by and among Mind Medicine (MindMed) Inc., Commodore Capital Master LP and Deep Track Biotechnology Master Fund, LTD.	8-K	10.1	October 17, 2024	001-40360
10.16	Amendment No. 1 to the Registration Rights Agreement, dated as of October 17, 2024, by and among Mind Medicine (MindMed) Inc., Commodore Capital Master LP and Deep Track Biotechnology Master Fund, LTD.	8-K	10.2	October 17, 2024	001-40360
10.17	Sales Agreement, dated as of June 28, 2024, by and between Mind Medicine (MindMed) Inc. and Leerink Partners LLC	S-3	1.2	June 28, 2024	001-280548
10.18#	Mind Medicine (MindMed) Inc. Employee Share Purchase Plan	S-8	99.5	June 28, 2024	001-280547
10.19#	Separation Agreement between Schond Greenway and Mind Medicine (MindMed) Inc., dated May 3, 2024, amended May 28, 2024	10-Q	10.3	August 13, 2024	001-40360
10.20	Form of Securities Purchase Agreement, dated as of March 7, 2024 between Mind Medicine (MindMed) Inc. and the Investors	8-K	10.1	March 11, 2024	001-40360

10.21	Form of Registration Rights Agreement, dated as of March 7, 2024 between Mind Medicine (MindMed) Inc. and the Investors	8-K	10.2	March 11, 2024	001-40360
10.22	Amendment No. 1 to the Registration Rights Agreement, dated as of October 17, 2024, by and among Mind Medicine (MindMed) Inc., Commodore Capital Master LP and Deep Track Biotechnology Master Fund, LTD.	8-K	10.2	October 17, 2024	001-40360
19.1*	Insider Trading Policy				
21.1	List of Subsidiaries of Mind Medicine (MindMed), Inc.	10-K	21.1	March 28, 2022	001-40360
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (included on signature page hereto).				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation	10-K	97.1	February 28, 2024	001-40360
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document contained in Exhibit 101)				

* Filed herewith.

** Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

# Indicates management contract or compensatory plan.

+ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mind Medicine (Mindmed) Inc,

Date: March 6, 2025

By: /s/ Robert Barrow

Robert Barrow
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Rob Barrow and Carrie F. Liao as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and substitution, for him or her and in his or her name, place, and stead, in any and all capacities (including his/her capacity as a director and/or officer of Mind Medicine (MindMed) Inc.) to sign any or all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents or any of them, or their, his, or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Robert Barrow **Robert Barrow**	Chief Executive Officer and Director (*Principal Executive Officer*)	March 6, 2025
/s/ Carrie F. Liao **Carrie F. Liao, CPA**	Chief Accounting Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 6, 2025
/s/ Carol Vallone **Carol Vallone**	Director	March 6, 2025
/s/ David Gryska **David Gryska**	Director	March 6, 2025
/s/ Roger Crystal **Roger Crystal, MD**	Director	March 6, 2025
/s/ Andreas Krebs **Andreas Krebs**	Director	March 6, 2025
/s/ Suzanne Bruhn **Suzanne Bruhn, PhD**	Director	March 6, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Barrow, certify that:

1. I have reviewed this Annual Report on Form 10-K of Mind Medicine (MindMed) Inc;

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 6, 2025

By: /s/ Robert Barrow

Robert Barrow
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Carrie F. Liao, certify that:

1. I have reviewed this Annual Report on Form 10-K of Mind Medicine (MindMed) Inc;

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 6, 2025

By: /s/ Carrie F. Liao

Carrie F. Liao
Principal Financial Officer and Chief Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Mind Medicine (Mindmed) Inc, (the "Company") on Form 10-K for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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.

Date: March 6, 2025

By: /s/ Robert Barrow

Robert Barrow
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Mind Medicine (Mindmed) Inc, (the "Company") on Form 10-K for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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.

Date: March 6, 2025

By: /s/ Carrie F. Liao

Carrie F. Liao
Principal Financial Officer and Chief Accounting Officer