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, 2022

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	**98-1582538**
(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: (650) 208-2454

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 Capital Market)

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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 30, 2022, the aggregate market value of the Registrant's common shares held by non-affiliates of the Registrant was $272.0 million based on the closing price of the Registrant's common shares, as reported by the Nasdaq Capital Market, on such date.

The number of the Registrant's common shares outstanding as of February 22, 2023 was 38,063,385.

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, 2022.

TABLE OF CONTENTS

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 MM-120, a proprietary, pharmaceutically optimized form of lysergide D-tartrate, MM-402 or R(-)-MDMA (together, our "lead product candidates"), MM-110 or zolunicant and any other product candidates (together with our lead product candidates, our "product candidates"), including statements regarding the timing of initiation and completion of trials or studies and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our reliance on the success of our investigational MM-120 product candidate;
- the timing, scope or likelihood of regulatory filings and approvals and 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;
- 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 identify, develop or acquire digital technologies to enhance our administration of our product candidates, if they should become approved and commercialized;
- 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 or any future 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, Canada, under the laws and regulations of the United Kingdom, and other jurisdictions;
- the effectiveness of our internal control over financial reporting;
- the effects of public health crises (such as the COVID-19 pandemic), including mitigation efforts and related adverse global economic effects on our business or operations and the potential disruption in the business and operations of third-party manufacturers, contract research organizations ("CROs"), other service providers, and collaborators with whom we conduct business;
- the impact of adverse global economic conditions, including fluctuation in interest rates, supply-chain disruptions and inflation, on our financial condition and operations;
- 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. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section titled "Risk Factors" 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://mindmed.co/investor-resources/). 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.

PART I

Item 1. Business.

Overview

We are a clinical stage 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 that unlock new opportunities to improve patient outcomes. We are 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 MM-120 and MM-402, our lead product candidates.

Our lead product candidate, MM-120, is a proprietary, pharmaceutically optimized form of lysergide D-tartrate that we are developing for the treatment of generalized anxiety disorder ("GAD"). MM-120 is also being studied in a subperceptual repeat administration dosing regimen for the treatment of attention deficit hyperactivity disorder ("ADHD"). Phase 2 studies for MM-120 in GAD and ADHD are ongoing and topline results from both trials are expected in late 2023.

Our second lead product candidate, MM-402, also referred to as R(-)-MDMA, is our proprietary form of the R-enantiomer of MDMA (3,4-methylenedioxymethamphetamine), 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 demonstrate its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggest that it has the potential to exhibit less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer. In the third quarter of 2022, our collaborator, University Hospital Basel ("UHB") in Switzerland, began conducting a Phase 1 investigator-initiated trial of R(-)-MDMA, S(+)-MDMA and R/S-MDMA in healthy volunteers to compare the tolerability, pharmacokinetics and acute subjective, physiological and endocrine effects of the three molecules. We expect to present results from a preclinical study of MM-402 in a model of ASD in the first half of 2023 and to initiate a Phase 1 study of MM-402 in 2023 to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM-402, and to evaluate early signals of efficacy to support our approach in targeting core symptoms of ASD.

Our third product candidate, MM-110, which has the non-proprietary name zolunicant, is 18-methoxycoronaridine, a congener of ibogaine, and is being developed for the treatment of opioid withdrawal. MM-110 is an $\alpha 3\beta 4$ nicotinic cholinergic receptor antagonist that has been tested in preclinical models of withdrawal and substance use disorders. In those studies, MM-110 was shown to reduce signs of opioid withdrawal, and to reduce self-administration of opioids, stimulants and ethanol. We completed a Phase 1 trial of MM-110 in late 2021; however, in the third quarter of 2022, we determined that any further clinical development of our MM-110 program will be subject to the pursuit of non-dilutive sources of capital and collaborations with third parties.

Beyond our clinical stage product candidates, we are pursuing a number of programs, primarily through external collaborations, through 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 and investigator-initiated trials ("IITs") of additional product candidates and research compounds with our collaborators. Our external research programs include a broad multi-year exclusive research partnership with UHB in Switzerland. Under the partnership, we have exclusive worldwide rights to data, compounds and patent rights associated with UHB's research on lysergide and a number of additional compounds, including data from preclinical studies and clinical trials investigating the effects of lysergide in patient populations and healthy volunteers. We also have an ongoing partnership agreement with MindShift Compounds AG to develop next-generation compounds utilizing the molecular backbone of classical psychedelics and empathogens. In addition, we have in the past and will continue to engage in other relevant research collaborations to support our ongoing development efforts and potential additions to our pipeline. Our research partnerships and IITs facilitate the advancement of our early-stage pipeline and support the potential identification of product candidates for additional company-sponsored drug development programs.

Our development strategy is closely complemented by a platform of digital medicine programs that we are developing to facilitate adoption, use, and access to our products, if they receive regulatory approval and are marketed. In particular, we are advancing multiple digital medicine programs, including software that is regulated as a medical device ("SaMD") by the U.S. Food and Drug Administration ("FDA"), as evidence-based therapeutic interventions for patients and HCPs to diagnose, prevent, manage or treat brain health disorders, or to facilitate the use of certain pharmaceutical products. Our lead digital medicine program, the MindMed Session Monitoring System ("MSMS") release readiness component, is a proprietary hardware/software platform designed to be used by HCPs during therapy sessions that involve pharmaceutical products with consciousness altering effects. Regulatory engagements with the FDA for the progression of this product candidate took place throughout late 2021 and 2022 and are expected to continue as we advance the development of MSMS and other potential SaMD programs. We are also continuing to evaluate the potential to pair these SaMDs, which may include wearables and the latest in machine learning, with pharmacotherapies and psychotherapies to give HCPs the ability

to optimize and better understand the patient journey and therapeutic outcomes from pre-care through after-care and to facilitate the adoption of certain of our product candidates, if they receive regulatory approval and are commercialized.

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, if any, pursuant to the regulations of the FDA and the legislation 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 drugs according to current Good Manufacturing Practices ("cGMP"), and conducting all trials and development in accordance with the regulations of the FDA, and other legislation in other jurisdictions.

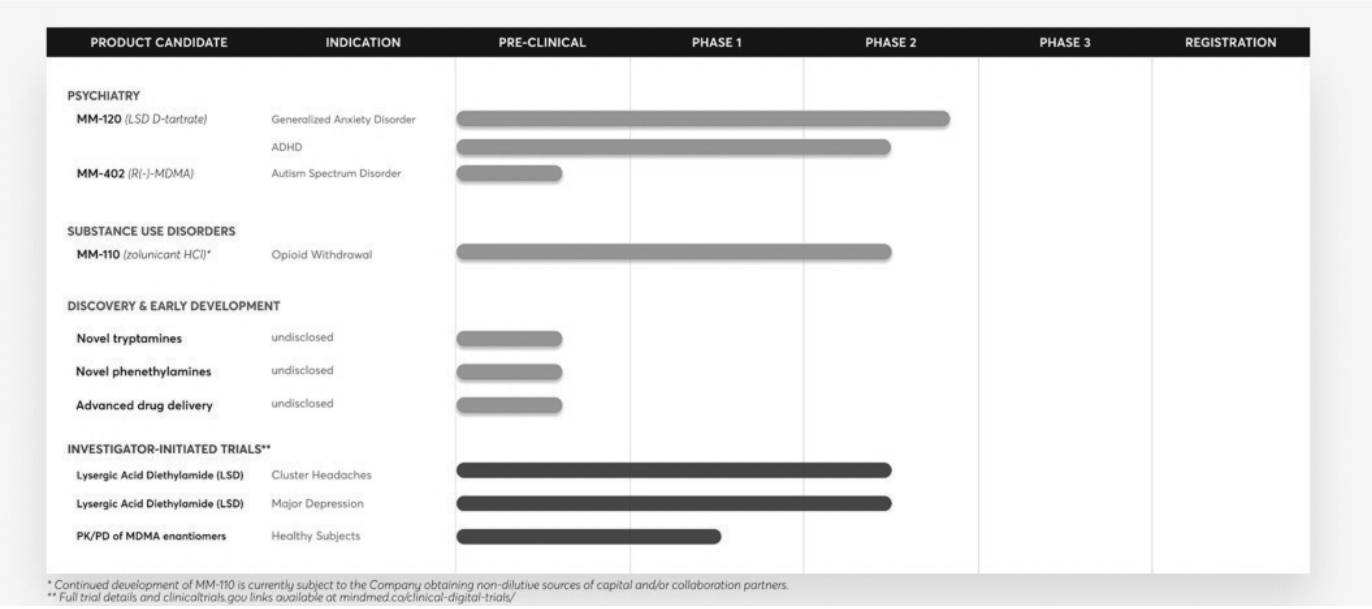
Our Strategy

Our mission is to be the global leader in the development and delivery of treatments that unlock new opportunities to improve patient outcomes for brain health disorders. We intend to accomplish our mission by leading the field in (1) research, (2) development, (3) digital medicine, and (4) commercialization, scalability and patient access. 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 the manufacture of commercial supplies;
- continue our research and development efforts to evaluate the potential for our existing 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 outside the United States, and determine the best strategic and business opportunities to advance our product candidates in these markets;
- continue to advance digital medicine programs, including conducting ongoing and planned clinical trials of our Session Monitoring System and other clinical and regulatory activities;
- continue to build, maintain, defend, leverage and expand our intellectual property portfolio, including by utilizing the strengths of our proprietary chemistry platform and 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 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:



MM-120 (Lysergide D-tartrate)

MM-120, or lysergide D-tartrate, is our proprietary product candidate, a pharmaceutically optimized form of lysergide D-tartrate being developed for GAD 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 is still under investigation, but recent neuroimaging studies have provided a plausible explanation for clinical efficacy in this disease area. 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—particularly prefrontal and default mode network regions—by lysergide may represent systems-level mechanisms underlying its therapeutic effects in anxiety and other brain health disorders. Lysergide has been investigated for its applications in the treatment of anxiety associated with terminal cancer, alcohol use disorder, opioid use disorder, and depression, among other conditions.

GAD is a chronic, often debilitating mental health disorder that affects approximately 6-10% 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, major depressive disorder ("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. Over the near-term, we intend to prioritize the clinical research program of MM-120 in psychiatric disorders. Given the expansive body of evidence on the clinical effects of lysergide across multiple brain health disorders, at the appropriate time in the future we intend to explore indications in other disease areas

As part of the development activities for MM-120, we are currently conducting two Phase 2 clinical trials:

- **Study MMED008:** In 2022, we initiated a Phase 2, randomized, double-blind, parallel-group, placebo-controlled, dose-finding study to assess the effect of four doses of MM-120 for the treatment of GAD patients; and

- **Study MMED007:** In December 2021, we initiated a randomized, double-blind, placebo-controlled Phase 2a proof of concept trial for the treatment of ADHD patients designed to assess the safety and efficacy of repeated low dose MM-120 administration.

We expect to report topline results from both the MMED008 and MMED007 trials in late 2023. In addition, there are a number of studies ongoing or planned to be conducted under our broad research collaboration with UHB.

MM-402 (R(-)-MDMA)

MM-402, or R(-)-MDMA, is our proprietary form of the R-enantiomer of MDMA (3,4-Methylenedioxymethamphetamine), 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 less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer. In the third quarter of 2022, our collaborator, UHB, began conducting a Phase 1 investigator-initiated trial of R(-)-MDMA, S(+)-MDMA and R/S-MDMA in healthy volunteers to compare the tolerability, pharmacokinetics and acute subjective, physiological and endocrine effects of the three molecules. We expect to present results from a preclinical study of MM-402 in a model of ASD in the first half of 2023 and to initiate a Phase 1 study of MM-402 in 2023 to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM-402, and to evaluate early signals of efficacy to support our approach in targeting core symptoms of ASD.

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, primarily 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, and IITs of novel biopharmaceuticals, both with and without perceptual effects, with our collaborators. Our partnered research programs include a broad multi-year exclusive research partnership with UHB and a partnership with Maastricht University in the Netherlands. We also have an active partnership with MindShift Compounds AG to develop and patent a portfolio of research compounds, both with and without perceptual effects, related to the phenethylamine, tryptamine, and ergoline chemical classes. These research collaborations include IITs, drug discovery activities, advanced drug delivery activities and the advancement of other research activities that seek to support the growth and advancement of our product development programs.

In addition to the above, our product candidate MM-110 (zolunicant or 18-methoxycoronaridine ("18-MC")) is being developed for the treatment of opioid withdrawal. Animal studies have demonstrated that MM-110 can significantly reduce drug self-administration of morphine, cocaine, methamphetamine, nicotine and alcohol, and ameliorate five of seven signs of opioid withdrawal. We completed a Phase 1 trial of MM-110 in late 2021, in which a total of 77 subjects were administered up to 325 mg of MM-110 twice (on a single day) or were administered up to 90 mg of MM-110 twice daily for seven days. Following feedback from the FDA related to the additional requirements to enable the conduct of a Phase 2a clinical trial in the US, in the third quarter of 2022, we determined that any further clinical development of our MM-110 program will be subject to the pursuit of non-dilutive sources of capital and collaborations with third parties.

Our Digital Medicine Programs

Our drug development strategy is closely complemented by a platform of digital medicine programs that we are developing to facilitate adoption, use, and access to our product candidates, if they receive regulatory approval and are commercialized. In particular, we are developing multiple digital medicine programs, including regulated SaMD products, as evidence-based therapeutic interventions for patients and HCPs to diagnose, prevent, manage or treat brain health disorders, or to facilitate the use of certain pharmaceutical products. We are also continuing to evaluate the potential to pair these SaMD products, which may include wearables and the latest in machine learning, with pharmacotherapies and psychotherapies to give HCPs the ability to optimize and better understand the patient journey and therapeutic outcomes from pre-care through after-care.

Our digital medicine programs are oriented to applications during two primary clinical periods: activities during a treatment session (referred to as "intrasession") and activities between treatment sessions (referred to as "intersession"). Each digital medicine programs consists of a platform that contains separate underlying components, some of which we anticipate will be within the scope of the Food, Drug & Cosmetic Act's definition of medical devices and others which we anticipate will not be regulated as medical devices. For the medical device products, we will engage with the FDA and other international regulatory authorities to receive guidance along the development pathway, culminating with a potential submission for regulatory clearance or approval. We expect that each SaMD program in development will be, for the purpose of FDA regulations, non-significant risk, Class I or Class II SaMD. In the EU, all digital product candidates are anticipated to be regulated as medical devices and/or combination products.

The intrasession monitoring platform may include components that provide in-session monitoring for safety, efficacy and additional interventions; clinician decision support for drug and non-drug therapeutic sessions; and predictive models linking interventions and treatment outcomes. The intersession monitoring platform may include components that support patient education, engagement, preparation and assistance; deep digital diagnosis that allows greater granularity to complement Diagnostic and Statistical Manual of Mental Disorders ("DSM") diagnoses; support for treatment selection: modality dose and timing; real world monitoring of trends for relapse prediction and re-treatment decisions; engagement in health maintenance behaviors; and AI models to inform psychotherapeutic intervention. Within our intersession monitoring platform, we have current product candidates that are being used in clinical studies for the detection and prediction of transdiagnostic agitation, and monitoring of patients with a range of psychiatric diagnoses. We also have products for measurement of anxiety disorders that are either currently collecting clinical data (from existing data sources), or are collecting, or will collect data in planned and ongoing clinical studies.

Our lead digital medicine program, the MindMed Session Monitoring System release readiness component is proprietary hardware/software platform designed to be used by HCPs during therapy sessions involving pharmaceutical products with consciousness altering effects. The MSMS consists of (i) a hardware-based device kit, which includes a tablet, smart phone, smart watch, blood pressure monitor, (ii) instructions for use, and (iii) a user-facing mobile application, which consists of MSMS installed on tablet for use by the HCP, and MSMS installed on smart phone and smartwatch, for use by the HCP's patients. The MSMS is designed to obtain inputs including heart rate, heart rate variability, audio, GPS location, accelerometer data, angular velocity, orientation, and number of steps. The MSMS then displays outputs of this patient data to the HCP on the HCP's tablet prior to dosing and continuously over the course of the treatment session. The MSMS is intended to provide information in a consolidated manner to the HCP supervising the consciousness altering session, in either an inpatient or outpatient setting, to support their ability to monitor and decide when a patient may be safely discharged from a treatment session. Regulatory engagements with FDA for the progression of this regulated product took place throughout late 2021 and 2022 and are expected to continue as we advance the development of MSMS and other potential regulated digital medicine programs.

Manufacturing & Supply

MM-120 and MM-402 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 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 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.

All materials required for the production of these product candidates are currently manufactured by other CDMOs or suppliers. 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 long-term supply or redundant supply of drug substance or drug product for our research compounds and product candidates. We intend to enter into a scalable, 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 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 MM-120 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.

Research and Development Collaborations

We have entered into several license agreements with respect to our research and development activities, which are described below.

University Hospital Basel - Liechti Lab Initiatives - Research Collaboration & Exclusive License

On April 1, 2020, we entered into a multi-year, exclusive collaboration with Dr. Matthias Liechti's lab at UHB, 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. Our ongoing research collaboration with the UHB Liechti Lab has generated a number of patent applications based on preclinical and clinical data.

We support ongoing and planned research programs, as well as certain clinical trials under the direction of Dr. Liechti. Dr. Liechti, as principal investigator, has primary responsibility for the research studies 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, UHB Liechti Lab may receive royalties and development revenue on any commercially marketed products developed through the collaboration.

MDMA Research

The UHB Liechti Lab has led multiple clinical trials investigating the safety and pharmacodynamics of MDMA. The cumulative data from the research conducted by the UHB Liechti Lab helps inform the design of our sponsored clinical trials and the assessment of development opportunities for MDMA or its derivatives as potential future development programs. We also continue to fund the UHB Liechti Lab's early-stage research activities aimed at exploring next-generation product candidates based on MDMA.

DMT Research

We are also funding the UHB Liechti Lab's research on DMT, a short-acting serotonergic tryptamine of the psychedelic drug class. This includes a Phase 1 randomized, double blind, placebo-controlled, five-period crossover trial in 30 healthy volunteers assessing various intravenous dosing regimens of DMT that was completed in late 2022. In order to potentially induce a stable DMT experience lasting one to two hours, various intravenous dosing regimens, including a starting dose and then a maintenance dose, were evaluated in this Phase 1 IIT. Results from this investigator-initiated study are anticipated to be published in 2023.

The human safety data and associated know-how gathered in this Phase 1 investigator-initiated trial will better enable our clinical team to design future potential product development programs based on DMT and could pave the way for future clinical trials of DMT or a derivative.

Ketanserin Research

We also funded a Phase 1 double-blind, placebo-controlled, random-order, two-period crossover clinical trial evaluating the effects of ketanserin on the acute response to lysergide in healthy subjects. This study intended to provide insights into the pharmacological activity of lysergide and the potential interaction between lysergide and co-administration with serotonin receptor antagonists. Results from this investigator-initiated study were published in November 2022 in the *International Journal of Neuropsychopharmacology* and demonstrated the potential of ketanserin to shorten and attenuate the perceptual effects of lysergide

Lysergide Research

Through our broad research collaboration with the UHB Liechti Lab, we have acquired exclusive rights to a body of historical and ongoing clinical trials assessing the clinical activity of lysergide in several brain health disorders including anxiety, depression and cluster headaches.

In December 2021, the UHB Liechti Lab completed an investigator-initiated trial assessing the efficacy of 200 micrograms lysergide (two doses) versus a placebo on anxiety and depression symptoms in 46 patients with clinically significant anxiety. The UHB Licheti

Lab published the results from the study in the peer-reviewed scientific journal Biological Psychiatry in September 2022. Topline results demonstrated the significant, rapid, durable, and beneficial effects of lysergide and its potential to mitigate symptoms of anxiety and depression with an acceptable tolerability profile.

We also supported a Phase 2 investigator-initiated trial evaluating lysergide for the treatment of MDD. The study evaluated the potential effects of two doses of lysergide (100 micrograms followed by 200 micrograms, separated by 4 weeks) on depression symptoms compared to a low dose of lysergide (25 microgram, two doses) in the control group. The study was completed in the second half of 2022 with topline results anticipated to be published in 2023.

Additionally, in the area of neurology, we are supporting a Phase 2 investigator-initiated trial evaluating the effects of lysergide to mitigate the signs and symptoms of cluster headaches in patients. Cluster headaches are a relatively uncommon primary headache disorder that are considered to be among the most severe forms of pain. The study began recruiting patients in early 2019 and is planned to be completed by the end of 2023.

Personalized Medicine Technology Research

We are also collaborating with the UHB Liechti Lab to research and develop technologies and analytics that seek to personalize psychedelic therapy treatment. One such research effort aims to better characterize the intrinsic and extrinsic factors that impact administration of MDMA, lysergide and other psychedelic compounds based on individual characteristics including age, gender, pharmacogenetics, personality traits, moods, metabolic markers and therapeutic drug monitoring. Through this collaborative research, we are seeking to advance our understanding of methods to predict and personalize the delivery of these compounds to enhance patient outcomes.

MindShift Compounds AG Initiatives

In February 2021, we entered into a partnership agreement with MindShift Compounds AG to develop and patent a portfolio of compounds, both with and without perceptual effects, related to the phenethylamine, tryptamine, and ergoline chemical classes. The objective of this partnership is to discover pharmaceutically optimized research compounds and product candidates. Drug discovery and synthesis activities by MindShift Compounds AG are ongoing and related patent applications have been and continue to be filed by us.

All intellectual property and pharmaceutical technology related to the synthesis processes developed through the collaboration are owned outright by us, and MindShift Compounds AG will provide all intellectual property related to the new psychedelic compounds exclusively to us.

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 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 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 will depend 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 patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We seek to obtain domestic 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.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by our issued patents, our pending patent applications or of patent applications we may file in the future. Moreover, we may have to participate in interference proceedings or derivation proceedings declared by the U.S. Patent and Trademark Office ("U.S. PTO"), or similar proceedings outside the United States, to determine priority of invention.

Patent Strategy and Applications

Our patent strategy includes pursuing protection for compositions of matter, methods of treatment, and diagnostic devices and analytics related to psychedelics. Our patent portfolio includes 26 pending U.S. applications, and 12 pending Patent Cooperation Treaty ("PCT") applications. Additionally, we plan to aggressively pursue patents in diagnostics with patient monitoring and analytics.

We hold pending patent applications in the United States and also under PCT. Our intellectual property holdings include, but are not limited to:

- U.S. and PCT applications covering compositions and methods of treating an individual with a psychedelic drug and reducing acute effects. If granted, patents based on these applications have a projected expiry date in 2041.
- U.S. and PCT applications covering methods of dosing and treating patients with a psychedelic with specific doses. If granted, patents based on these applications have a projected expiry date in 2041.
- U.S. and PCT applications relating to lysergide covering methods of treatment, analytical methods, compositions of matter, and dosage formulations. If granted, patents based on these applications have a projected expiry date in 2041 and 2042.
- U.S. and PCT applications covering a method of enhancing positive effects of a psychedelic. If granted, patents based on these applications have a projected expiry date in 2041.
- U.S. and PCT applications relating to MDMA covering methods of dosing MDMA in treating patients, methods of reducing adverse effects, and compositions of matter. If granted, patents based on these applications have a projected expiry date in 2041.
- U.S. and PCT applications covering methods of treatment with DMT. If granted, patents based on these applications have a projected expiry date in 2041.
- U.S. and PCT applications covering analytical methods with psilocybin. If granted, patents based on these applications have a projected expiry date in 2041.
- Provisional applications relating to psilocin covering compositions of matter and methods of treatment.
- U.S. and PCT applications covering mescaline derivatives, and methods of treatment with mescaline and mescaline derivatives If granted, patents based on these applications have a projected expiry date in 2042.
- U.S. and PCT applications covering compositions of matter and methods of treatment with 18-Methoxycoronaridine (18-MC) salt. If granted, patents based on these applications have a projected expiry date in 2040. Provisional applications covering methods of treatment with various psychedelics.
- Provisional applications covering systems and methods for monitoring patients and analyzing mental state.

Patent Term

The base term of a U.S. patent is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the U.S. PTO. In some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent.

The term of a U.S. patent may also be eligible for patent term extension 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 shorter of five years beyond the non-extended expiration of the patent or 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 pharmaceutical products receive FDA approval, we expect 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.

Competition

The biopharmaceuticals industry is highly competitive. There are many public and private companies, universities, governmental agencies and other research organizations actively engaged in the research and development of products that may be similar to our product candidates or address similar markets. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase.

Our most advanced development candidate, MM-120, is in Phase 2b development for GAD and in Phase 2a development for ADHD. Patients with GAD are typically treated with a variety of anxiolytic and antidepressant medications, including selective serotonin reuptake inhibitors, serotonin–norepinephrine reuptake inhibitors and benzodiazepines. If successfully developed and approved, MM-120 may also face competition from esketamine, which is approved in the treatment of treatment resistant depression and from ketamine which is not approved but whose off-label use is rapidly growing. A number of companies are developing product candidates intended for the treatment of GAD, including CYB004 (a serotonin receptor agonist) being developed by Cybin Inc. and zuranolone (a positive allosteric modulator of the $GABA_A$ receptor) which is being developed by Sage Therapeutics, Inc. In addition, ATAI Life Sciences N.V. is currently studying deuterated etifoxine (GRX-917), the non-deuterated form of which has been commercially available in France for the treatment of GAD since 1979. Patients with ADHD are generally treated with behavioral interventions, pharmacotherapies, combination treatments, school-based interventions, social skills training, and psychotherapies. Currently available pharmacotherapies include psychostimulants, selective norepinephrine reuptake inhibitors, and alpha-2-adrenergic antagonists. Each of these available therapies could represent competition for MM-120 if it were to be approved for the treatment of ADHD.

Among other organizations working on novel biopharmaceuticals focused on modulation of the serotonin and dopamine systems, we also face competition from a number of companies, including ATAI Life Sciences N.V, Compass Pathways plc, GH Research plc and others. ATAI Life Sciences N.V is developing multiple product candidates that are in various phases of development for the treatment of psychiatric and substance use indications. Compass Pathways plc is developing COMP360 (a proprietary formulation of psilocybin) that is in Phase 3 clinical trials for treatment-resistant depression and is being studied in other psychiatric indications. GH Research plc is developing GH001, GH002 and GH003 that are in Phase 1/2 clinical trials for treatment-resistant depression. There are also many other public and private companies developing therapeutics from the psychedelic drug class at various stages of development.

Our other lead product candidate, MM-402, 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, MM-402 may face competition from Multidisciplinary Association for Psychedelic Studies (MAPS), which has a (+/-)-MDMA product candidate in clinical development for the treatment of social anxiety in the ASD population. MAPS also has a (+/-)-MDMA product candidate in Phase 3 clinical trials for the treatment of post-traumatic stress disorder. 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., Otsuka Pharmaceutical Co. Ltd., Jazz Pharmaceuticals plc, Janssen Pharmaceuticals, Inc., Sage Therapeutics, Inc. 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.

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the U.S. The process required by the FDA before a drug 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;
- Submission to the FDA of an 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 practice ("GCP"), 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 non-clinical and/or clinical trial sites that generated the data in support of the NDA; and

- Payment of applicable user fees and FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.

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.

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 before or 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.

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. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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

Clinical trials are generally conducted in three 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 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 as a condition of approval of an NDA.

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.

NDA and FDA Review Process

The 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, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an 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 and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be offered for sale in the U.S.

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. Under the Best Pharmaceuticals for Children Act, the FDA may also issue a Written Request asking a sponsor to conduct pediatric studies related to a particular active moiety; if the sponsor agrees and meets certain requirements, the sponsor may be eligible to receive additional marketing exclusivity for its drug product containing such active moiety.

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. Once 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 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 cGMPs. 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 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 likely re-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.

The FDA typically requires that certain contraindications, warnings or precautions be included in the product labeling, and 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 assure the safe use of the drug. 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 medication guides, physician communication plans, or 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. 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.

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 and provides meaningful therapeutic benefit over existing treatments. 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 and may request the FDA to designate the drug as a Breakthrough Therapy based on preliminary clinical evidence which meet the criteria 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.

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 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 may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective 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 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 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. 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, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, 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. 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. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, 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 clinical trials. As with new NDAs, the review process is often significantly extended by FDA requests for additional information or clarification. 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.

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. These 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. 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.

Digital Therapeutics/Software as a Medical Device

Software applications such as the digital therapeutics that we are developing may meet the definition of a medical device and be subject to FDA pre-market authorization, depending on their classification and software function. FDA has issued guidance and referenced international principles established by the International Medical Device Regulators Forum for the clinical evaluation of SaMD, which refers to software that is intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. We expect that our digital therapeutics in development will be, for the purpose of FDA regulations, non-significant risk, Class I or Class II medical devices. Certain clinical decision support ("CDS"), software, is exempt from the definition of a medical device, or under FDA guidance, is subject to a policy of enforcement discretion.

Other 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 U.S. Drug Enforcement Administration (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 makes it illegal for 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 (including any kickback, bribe or rebate), 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 or order, of a particular 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. 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 the potential for 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, or 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), 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" – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service 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, use, or disclose 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 and civil 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, being 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 may 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 must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to herein as the "ACA"). If 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 to report development costs and pricing information when prices are increased. Penalties for late or faulty reporting can reach $10,000 per day. 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 and Controlled Substances Import and Export Act.

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 each other 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 U.S. PTO, 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.

European Union Drug Development

In the European Economic Area ("EEA"), 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 competent regulatory authorities in the EU has been obtained.

Similar to the U.S., the various phases of non-clinical and clinical research in the EU 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 EU, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products, and increased obligations on sponsors to publish clinical trial results.

In the EU, pediatric data or an approved Pediatric Investigation Plan ("PIP"), or waiver, is required to have been approved by 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 approved 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 (which is comprised of 27 Member States of the EU plus Norway, Iceland and Liechtenstein), 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, orphan medicinal products, 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 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. 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 approval. 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. Breaches of the rules governing the promotion of medicinal products in the EU could be penalized by civil, criminal or administrative sanctions, which may include fines and imprisonment. These laws may further limit or restrict the advertising and promotion of medicinal products to healthcare professionals. 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.

European Union Medical Device Development, Approval 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 SaMD 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 SaMD, 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 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 intervention 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 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 prepared and signed a related EC Declaration of Conformity.

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 products 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. 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 sets out the regulatory framework for medical devices in the EU. The Competent Authorities of each EU Member State oversee the implementation of the MDR within their jurisdiction. Devices are classified in accordance with their perceived risks in a manner similar to the United States risk classification system. Before a medical device can be marketed in the EU it must undergo a conformity assessment procedure after which the manufacturer may affix the CE mark on the devices. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Once the Notified Body has issued a Certificate of Conformity, the manufacturer has drawn up the Declaration of Conformity and affixed the CE mark the device can be sold throughout the European Union. The MDR also imposes post-marketing requirements including among others market surveillance. 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 a medicinal product as an integral part 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 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 as a single use drug delivery system, it is regulated as a medicinal product. In this case, the relevant General Safety and Performance Requirements, or 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

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. 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 will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the EU-UK Agreement, the EU and the UK will recognize 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 for a period of at least two years until January 1, 2024. 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 existing EU legislation (as implemented into UK law, through secondary legislation). However, it is currently unclear to what extent the UK will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation last year on January 31, 2022.

As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. 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 centralized procedure and instead must follow one of the UK national authorization procedures to obtain a marketing authorization to market products in the UK. For a three year period from January 1, 2021, MHRA may rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EU Member States to be granted in Great Britain. Post Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in 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 will be 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 will, however, continue to be covered by the regulations governing CE Marks (a CE Mark or a CE Mark and UKCA mark will be required to place products on the Northern Ireland market). CE Marks will in principle continue to be recognized in Great Britain for medical devices until June 30, 2024, however all 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 nature of any new regulation in the UK is uncertain, and as such, we may experience delays in obtaining future access to the UK. and other European markets. The UK's departure from the EU has also impacted customs regulations and impacted timing and easy of shipments into the EU from the UK.

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 ability to collect, analyze and transfer 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 temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, 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. Mechanisms to allow for the transfer of personal data from the EEA to the U.S. are subject to legal challenges. The most common, currently authorized procedure to transfer personal data out of the EU, the European Commission's Standard Contractual Clauses ("SCCs") may come under increased scrutiny. Following the European Court of Justice's ruling, the European Data Protection Board issued a statement providing among other things that it is a primary responsibility of the exporter and the importer, when considering whether to rely on Standard Contractual Clauses to export data from the EU to third countries, to ensure that these third countries maintain a level of protection that is essentially equivalent to that guaranteed by the GDPR in light of the EU Charter of Human Rights. Companies may need to revise their Standard Contractual Clauses in light of the July 16, 2020 judgement. Companies that have not taken steps to demonstrate that their Standard Contractual Clauses and personal data recipients in the U.S. are suitable to transfer to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules.

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.

Rest of the World Regulation

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. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the Inflation Reduction Act (the "IRA"), among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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. 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 healthcare practitioner 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.

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 Regulation"), which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the 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 Regulation 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 health technologies assessment. The proposed regulation is intended 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. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025.

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.

Controlled Substances

The federal Controlled Substances Act of 1970 (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, 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 DEA categorizes controlled substances into one of five schedules—Schedule I, II, III, IV or V—with varying qualifications for listing 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 listed 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.

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).

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 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.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced 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. 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 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, amended by Regulation (EU) No 1258/2013, which regulates intra-Community trade and 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, amended by Regulation (EU) No 1259/2013. 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 NPS, under the procedures set out in the Regulation (EU) 2017/2101.

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 of December 31, 2022, our personnel includes 48 full-time employees, including 27 in research and development, 6 in digital development, 15 in general and administrative and no part-time employees. We also utilize independent 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, 2022, we consider our personnel relations to be good.

Corporate Information

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") between 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) Inc."

In February 2021, we completed the acquisition of HealthMode, Inc., a digital medicine and therapeutics company that used artificial intelligence enabled digital measurement to increase the precision and speed of clinical research and patient monitoring. The acquisition enabled us to build our digital medicine division.

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 West Hastings Street, Suite 1700, Vancouver, British Columbia V6E 2E9. We also maintain offices in Durham, North Carolina.

Our common shares are traded on Nasdaq Capital Market under the symbol "MNMD". Our common shares are also traded on the NEO Exchange in Canada under the symbol "MMED".

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.sedar.com).

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.

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 initiated or completed any large-scale or 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 brain health 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 current or any future 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 current or any future product candidates on a timely basis or at all, which will adversely affect our business.

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

- 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, such as the United States, the UK and the rest of Europe, 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, and our financial condition. 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 NDA 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.

- The successful commercialization of our product candidates or any future 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 or any future 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.

- 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 or any future 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.

- 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.

Risks related to our financial position and need for additional capital

We have a limited operating history, have not initiated or completed any large-scale or 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, MM-120, is in a Phase 2b trial for GAD and a Phase 2a trial for ADHD, and we expect to initiate our first clinical trial of MM-402 in 2023. Additionally, in the third quarter of 2022, we paused development of MM-110, subject to the receipt of non-dilutive sources of capital or collaborations with third parties. To date, we have devoted substantially all of our resources to research and development activities, including our development programs and other preclinical programs, acquiring rights or in-licensing of external programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, providing general and administrative support for these operations and establishing our digital medicine programs through the acquisition of HealthMode, Inc.

We have not yet demonstrated our ability to successfully initiate and complete any large-scale or 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 in 2022, 2021 and 2020. We incurred net losses of $56.8 million and $93.0 million for the years ended December 31, 2022 and December 31, 2021, respectively, and as of December 31, 2022, we had an accumulated deficit of $194.5 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. In the future, 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, ADHD, 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;
- continue to develop our regulated and unregulated digital medical products, product candidates, and devices;
- 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 MM-120 and MM-402;
- seek additional indications for our investigational product candidates and discover and develop any future product candidates, including current and future 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 MM-120 and MM-402 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, Switzerland, the United Kingdom, the European Union 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. and Canada, 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 or any future product candidates, training a sufficient number of qualified healthcare practitioners to deliver our investigational 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 U.S. Food and Drug

Administration, the EMA, the UK's medicines regulator, the MHRA, or other comparable foreign authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of our investigational product candidates or any future 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.

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 and patients, the ability to obtain reimbursement at any price 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 MM-120, MM-402 and our other current and future product candidates;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of MM-120, MM-402 and our other current and future 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 collaborators;
- 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, WHO and international counterparts;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, in the United States, Canada and internationally;
- 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 current 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, the EMA, the MHRA or other regulatory agencies 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 MM-120, MM-402 or any other product candidate before we receive marketing approval from the FDA. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2022, we had $142.1 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our operations into the first half of 2025. Our estimate as to how long we expect our existing cash to be able to continue 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. We currently do not have any committed external source of funds. 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 current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA, the European Commission, the MHRA 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 MM-120 and MM-402) or any other current or future 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 current product candidates and any future 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 investigational product candidates or any future product candidate, or we may be unable to take advantage of future business opportunities. For example, in the third quarter of 2022, we paused the development of MM-110 subject to our receipt of non-dilutive sources of capital or collaborations with third parties. 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 current product candidates or to any future 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 alliances 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. 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. For example, at December 31, 2022, we had an effective shelf registration statement filed with the SEC in May 2022 registering $200.0 million of equity securities, of which $100.0 million was reserved for sales under our at-the-market equity offering program (the "ATM"). At December 31, 2022, $137.9 million remained available for issuance under the shelf registration statement, of which $67.9 million is reserved for sales under the ATM. 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 limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and 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 investigational 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 MM-120, MM-402, or any of our current or future product candidates will receive regulatory approval or that our product candidates will be successfully commercialized even if they receive regulatory approval. If we were required to discontinue development of our product candidates, or if MM-120 or MM-402 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, the DEA, the European Commission and the EMA, the MHRA and other foreign regulatory authorities including national competent authorities of EU Member States. Failure to obtain regulatory approval in the United States, the EU 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 and any future 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 planned clinical trials or future 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 current and any future 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 our current or any future product candidates are approved;
- entering into collaborations to further the development of our product candidates and any future product candidates;
- obtaining and maintaining patent and trade secret protection and/or regulatory exclusivity for our product candidates and any future product candidates;
- successfully launching commercial sales of our product candidates and any future product candidates, if approved;
- acceptance of our product candidates and any future product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates and any future 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 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 current product candidates or any future product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current product candidates or any future 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 will be marketed, such as the United States, the United Kingdom and the European Union, 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, as well as other substances, are listed by the DEA as "Controlled Substances" or scheduled substances, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act (the "CSA"), specifically as Schedule I substances. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances. 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. Pharmaceutical products approved for 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. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Further, most, if not all, state laws in the United States classify lysergide and MDMA as Schedule I controlled substances. For any product containing lysergide, MDMA or any other Schedule I substances to be available for commercial marketing in the United States, lysergide, MDMA or any other Schedule I substances must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Commercial marketing in the United States will also require scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while lysergide, MDMA and other compounds used in our product candidates are Schedule I controlled substances, products approved by the FDA for medical use in the United States that contain lysergide, MDMA or other Schedule I controlled substances should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when MM-120 and MM-402 receive FDA approval, we anticipate that the DEA will make scheduling determinations and place them in a schedule other than Schedule I in order for them to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule under the CSA. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may introduce a delay into the approval and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will require DEA to conduct notice and comment rule making including issuing an interim final rule. Such action will be subject to public comment and requests for hearing which could affect the scheduling of these substances. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), at the federal level, such substances would also require scheduling determinations under state laws and regulations.

If approved by the FDA, and if the finished dosage form of any of our product candidates is listed by the DEA as a Schedule II, III, or IV controlled substance, 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, the scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of our product candidates in the United States. Furthermore, the FDA, DEA, or any foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of our product candidates and any future product candidates containing controlled substances. 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 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 investigational 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 the product 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 our product candidates nor any of their drug substances could be imported, 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, because of a Schedule II classification or voluntarily, 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, 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 MM-120, MM-402, or any other current or future product candidate, may not be sufficient to complete clinical trials or meet 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 and any future 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.

The potential reclassification of Schedule I substances, including lysergide and MDMA in the United States and similarly in foreign jurisdiction could create additional regulatory burdens on our operations and negatively affect our results of operations.

If Schedule I substances, including lysergide and MDMA, other than in the FDA-approved formulation, are rescheduled under the CSA as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), the ability to conduct research on our product candidates would most likely be improved. However, rescheduling such Schedule I substances may materially alter enforcement policies across many federal agencies, primarily the FDA and DEA. The FDA is responsible for ensuring public health and safety through regulation of food, drugs, supplements, and cosmetics, among other products, through its enforcement authority pursuant to the FDCA. The FDA's responsibilities include regulating the ingredients as well as the marketing and labeling of drugs sold in interstate commerce. Because it is currently illegal under federal law to produce and sell Schedule I substances, including lysergide and MDMA, and because there are no federally recognized medical uses, the FDA has historically deferred enforcement related to Schedule I substances to the DEA. If Schedule I substances were to be rescheduled to a federally controlled, yet legal, substance, the FDA would likely play a more active regulatory role. The DEA would continue to be active in regulating manufacturing, distribution and dispensing of such substances. The potential for multi-agency enforcement post-rescheduling could threaten or have a materially adverse effect on our business.

In jurisdictions following a similar approach as the US, potential changes to the classification lysergide and MDMA may similarly facilitate research but may also result in regulatory hurdles and increased scrutiny by multiple regulatory authorities.

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 may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates and any future product candidates we may develop. Opponents of these product candidates may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to 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. Adverse publicity from misuse of lysergide or MDMA, or any other substance that underlies our current or future product candidates or are part of the same drug or chemical class, may adversely affect the commercial success or market penetration achievable by our product candidates. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our investigational product candidates or any future product candidates.

If our product candidates or any future product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of the safety and quality of our product candidates. We may face limited adoption if third-party treatment sites, healthcare practitioners, and patients are unwilling to try such a novel treatment. There has been a history of negative media coverage regarding psychedelic substances, including lysergide and MDMA, which may affect the public's perception of our product candidates. In addition, lysergide elicits intense psychological experiences, and this could deter patients from choosing this course of treatment. We could be adversely affected if we were subject to negative publicity or if any of our product candidates or any similar therapies distributed by other companies prove to be, or are asserted to be, harmful to patients. 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 internationally regarding the medical benefits, viability, safety, efficacy and dosing of psychedelic drugs remains in early stages. There have been relatively few clinical trials on the benefits. 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, ADHD, 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 current or any future 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 current or any future 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 or any future 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 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 current and future 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;

- 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;

- adding new clinical trial sites;

- availability of adequately trained healthcare practitioners 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 any future 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;

- 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; and

- 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.

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, the national competent authorities of the EU Member State, the MHRA 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, the national competent authorities of the EU Member State, the MHRA 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 current or future product candidates and those relating to the class to which lysergide, MDMA and other Schedule I controlled substances or any future 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 lysergide, MDMA or any other current or future product candidates, the commercial prospects of our product candidates or any future 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 MM-120, MM-402 or any other current or future 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 or any future 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 or any future 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 or any future product candidates and impair our ability to commercialize our product candidates or any future 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 any future product candidates or result in the development of our product candidates or any future product candidates being stopped early.

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 its 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.

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, including Australia, the United Kingdom, Switzerland and the Netherlands, for any of our product candidates, 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 MM-120, MM-402 or other product candidates. We believe that the data from previous studies will support the filing of additional INDs to enable us to undertake additional clinical studies of our current 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. 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 the Corporation's opportunity to generate revenue.

Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of MM-120, MM-402, or any other current or future 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 or future 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 and, because our investigational 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. 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 current clinical trials or any other future 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 investigational 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 ongoing or future clinical trials are inconclusive with respect to the efficacy of MM-120, MM-402 and any other current or future product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with MM-120, MM-402 and any other current or future 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 MM-120, MM-402 and any other current or future 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, the EMA 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. To the extent that the results of the trials are not satisfactory to the FDA, the EMA 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 MM-120, MM-402 and any other current or future 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 MM-120, MM-402 or any other current or future product candidates, we may not be able to continue our operations. Even if regulatory approval is secured for MM-120, MM-402 or any other current or future 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.

Interim, top-line 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, top-line 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 subjects have been enrolled, but before completion of the trial. Similarly, we may report top-line or preliminary results of primary and key secondary endpoints before the final trial results are completed. Interim, top-line and preliminary data from our clinical trials may change as more patient data or analyses become available. Preliminary, top-line or interim data from our clinical trials are not necessarily predictive of final results. Interim, top-line 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, top-line 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, top-line 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, 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 top-line 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 MM-120, MM-402 or any other current or future product candidate, our business, operating results, prospects or financial condition may be harmed.

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

We have not submitted a NDA, to the FDA, or a marketing authorization application ("MAA"), to the EMA or the MHRA. Before obtaining regulatory approvals for the commercial sale of any current and any future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that any current and any future product candidates are 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, the European Commission, the MHRA 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. 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. We have not obtained regulatory approval for any of our product candidates. It is possible that neither our current nor any future product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA, the EMA, the MHRA or other comparable foreign regulatory authorities may disagree with, question or request changes in the design or implementation of our clinical trials;
- the FDA, the EMA, the MHRA or other comparable foreign regulatory authorities may determine that MM-120, MM-402 or any other current or future 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, the EMA, the MHRA or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates or any future product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA, the MHRA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates or any future product candidates may not be sufficient to support the submission of an NDA or other submission, or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA, the MHRA 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, the EMA, the MHRA 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, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any current or any future product candidates, which would significantly harm our business, results of operations and prospects. The FDA, the EMA, the MHRA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our current or any future product candidates. Even if we believe the data collected from clinical trials of our current or any future product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, the MHRA or any other regulatory authority. If MM-120, MM-402 or any other current or future product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process, 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 current or any future 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 or any future product candidates.

Even if MM-120, MM-402 or any other current or future 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 or any future product candidates.

If the FDA, the European Commission, the MHRA or a comparable foreign regulatory authority approves MM-120, MM-402 or any other current or future 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 cGMPs, 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 MM-120, MM-402 or any other current or future product candidates, withdrawal of the product from the market, or product recalls;
- untitled and warning letters, or holds on clinical trials;
- refusal by the FDA, the EMA, the MHRA 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 MM-120, MM-402 or any other current or future 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 MM-120, 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, requiring 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 current product candidates and any future product candidates we may develop 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 MM-120, MM-402 or any other current or future product candidates or following approval, if any, we may need to abandon our development 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 current product candidates or any future 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, the European Commission, the MHRA or other comparable foreign authorities. We or regulatory authorities may also learn of and take similar actions based on side effects related to MM-120, MM-402, any other current or future 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 studies may show that MM-120, MM-402 or any other current or future 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, the national competent authorities of the EU Member States, the MHRA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of MM-120, MM-402 or any other current or future 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 human clinical studies. 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 MM-120, MM-402 or any other current or future 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 subjects 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 MM-120, MM-402 or any other current or future 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 studies may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product candidates, new risks and side effects associated with our product candidates may be discovered. There have been other products and therapies that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of therapies from the market, and our product candidates and any future product candidates may be subject to similar risks. We might have to withdraw or recall our product candidates and any future product candidates from the marketplace. We may also experience a significant drop in the potential future sales of our product candidates or any future product candidates if and when regulatory approvals for such product candidates are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product candidates, if any, or substantially increase the costs and expenses of commercializing and marketing our investigational product candidates and any future product candidates.

Additionally, if our product candidates or future 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 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 or any future product candidates.

Even if we obtain FDA, European Commission or MHRA approval for MM-120, MM-402 or any other current or future product candidates that we may identify and pursue in the United States, the EU or the UK, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions, 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 regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, 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 and any future product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA, European Commission or MHRA 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 current product candidates or any future 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 current product candidates and any future product candidates will be harmed.

The results of preclinical studies and early-stage clinical trials of our product candidates or any future product candidates may not be predictive of the results of later stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of MM-120, MM-402 or any other current or future product candidates. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

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 MM-120, MM-402 and MM-110, 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 MM-120 and MM-110 (prior to when we paused development of MM-110) have previously been treated with other drugs or therapies. All of these factors may make it difficult to assess the prior use or the overall efficacy of our product candidates, including MM-120 and MM-402.

We depend on enrollment of patients in our clinical trials for our product candidates and any future 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;
- the willingness or availability of patients to participate in our trials, including due to impacts of public health emergencies such as the COVID-19 pandemic;
- perceived risks and benefits of our approach to treatment of indication;
- 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 MM-120, MM-402 or any other current or future 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 MM-120, MM-402 or any other current or future 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 MM-120, MM-402 or any other current or future 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 product candidates. 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 product substances. 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 healthcare practitioners to meet the demand for psychedelic treatment sessions (including with MM-120 and any other current or future product candidate within the therapeutic class);
- the ability of our healthcare practitioners 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 any future product candidates;
- 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.

Our current and potential future digital technologies may not be successful, which may adversely affect our business, financial condition and results of operation.

We currently employ or are developing digital technologies to collect data, educate patients and healthcare practitioners, collect digital phenotyping information, and harness artificial intelligence. We are expanding our research into digital technology to complement and augment our current or future product candidates, and may work with technology companies or other third parties to acquire or develop new technologies. Our efforts to develop, acquire or integrate these technologies will involve significant time, costs, and other resources, and may divert our management team's attention and focus from executing on other key elements of our strategy. If our efforts to develop, acquire or integrate these digital technologies are unsuccessful, it may have a materially adverse impact on our business, future prospects and financial position.

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

We may never have a product candidates that is commercially successful. To date, we have no product candidates authorized for marketing. Our current or future product candidates require or will require further clinical investigation, regulatory review, significant market access and marketing efforts and substantial investment before it 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 historic 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 future 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 healthcare professionals, patients and healthcare 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 healthcare payors, and the willingness of patients to pay out of pocket in the absence of healthcare payor coverage or adequate reimbursement;
- the willingness of the target patient population to try, and of healthcare professionals 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;

- any restrictions on the use, sale or distribution of our product candidates or any future 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 or any future product candidates fail to gain 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 current or future 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 current and any future 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 have 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 MM-120, MM-402 or any other current or future product candidates. If third-party sites fail to recruit and retain a sufficient number of HCPs or effectively manage 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 or any future 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 or any future 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. The HCPs might also administer unauthorized therapies to patients using illegal compounds in "underground" clinics. Such illegal activities would put the patients at risk and subject us to potential liabilities, litigations, regulatory proceedings and reputational harm. If this were to occur, we may face serious setbacks for our commercialization process and our financial condition and results of operations would be materially harmed.

The commercialization of our current or future product candidates is dependent on our relationships with affiliated professional entities, which we do not own, to provide physician services, and our business would be adversely affected if those relationships were disrupted.

There is a risk that U.S. state authorities in some jurisdictions may find that our contractual relationships with our affiliated providers violate laws prohibiting the corporate practice of medicine and certain other health professions. These laws generally prohibit the practice of medicine and certain other health professions by lay persons or entities and are intended to prevent unlicensed persons or entities from interfering with or inappropriately influencing the professional judgment of clinicians and other healthcare practitioners. The professions subject to corporate practice restrictions and the extent to which each jurisdiction considers particular actions or contractual relationships to constitute improper influence of professional judgment vary across jurisdictions and are subject to change and evolving interpretations by state boards of medicine and other health professions and enforcement agencies, among others. As such, we must monitor our compliance with laws in every jurisdiction in which we operate on an ongoing basis, and we cannot guarantee that subsequent interpretation of the corporate practice laws will not further circumscribe our business operations. State corporate practice restrictions also often impose penalties on health professionals for aiding a corporate practice violation, which could discourage clinicians or other licensed professionals from participating in our network of providers. Any difficulty securing clinicians to participate in our network could impair our ability to provide product candidates and could have a material adverse effect on our business.

Corporate practice restrictions exist in some form, whether by statute, regulation, professional board or attorney general guidance, or case law, in over 40 U.S. states, though the broad variation between jurisdictions with respect to the application and enforcement of the doctrine makes establishing an exact count difficult.

Because of the prevalence of corporate practice restrictions on medicine, we contract for provider services and other services provided by our network of providers through various agreements, such as service agreements, rather than employ providers. We expect that these relationships will continue, but we cannot guarantee that they will. The arrangement in which we have entered to comply with state corporate practice of medicine doctrines could subject us to additional scrutiny by federal and state regulatory bodies regarding federal and state fraud and abuse laws. In addition, a material change in our relationship with the providers, whether resulting from a dispute among the entities, a change in government regulation, or the loss of these affiliations, could impair our ability to provide product candidates and could have a material adverse effect on our business, financial condition and results of operations.

We may become exposed to costly and damaging liability claims, either when testing our product candidates or any future 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 current and future use of our product candidates or any future 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 future product candidates or any prospects for commercialization of our product candidates or any future 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 MM-120, MM-402 or any other current or future 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 MM-120, MM-402 or any other current or future 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 or any future 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 or any future 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 MM-120, MM-402 or any other current or future product candidates containing lysergide, MDMA and other Schedule I controlled substances are approved and scheduled by regulatory authorities to allow their commercial marketing, the ingredients in such product candidates would likely continue to be Schedule I, or the state or foreign equivalent. Violations of any federal, provincial state or foreign laws 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 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 or defense of any such matters or our final resolution 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. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

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 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. state or local laws or the laws of other countries and regions 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 state and local laws with respect to Schedule I substances, such as lysergide and MDMA does not absolve us of potential liability under U.S. federal law, EU law or English law, 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.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers may be subject, directly or indirectly, 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 current and future operations may be directly, or indirectly through our relationships with investigators, healthcare professionals, customers and third-party payors, subject 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 (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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 definition of the "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. 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. On December 2, 2020, the Office of Inspector General ("OIG"), published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rules (with exceptions) became effective January 19, 2021.

- 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 to, or approval by Medicare, Medicaid, or other federal healthcare programs, 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 fines 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"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any

healthcare benefit program or 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 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 U.S. federal legislation commonly referred to as 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 Europe 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, especially in light of the lack of applicable precedent and regulations. 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 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, the federal 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, as amended by HITECH, 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 ("CCPA") imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents 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. In addition, the California Privacy Rights Act of 2020 ("CPRA"), which came into effect on January 1, 2023, expands the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of an enforcement action. Other states have enacted similar comprehensive data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. 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 ("PIPEDA") and various related director provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. In addition, the EU GDPR and the United Kingdom's GDPR ("UK GDPR") impose strict requirements for processing the personal information of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on information processing, as well as fines of up to 20 million Euros or 4% of annual global revenue, 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, such as the United States, which the European Commission does not consider to provide an adequate level of data privacy

and security. 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. In addition, laws in the UK similarly 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 may be subject to contractual obligations and 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, 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.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. 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 fail (or be perceived to have failed) to do so. 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 enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans 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 current product candidates or any future 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 or any future 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 current or any future product candidates, if approved. As Schedule I substances under the CSA, lysergide and MDMA are deemed to have no accepted medical use and therapies that use these substances are precluded from reimbursement in the United States. 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 or any future 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, European countries 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.

We intend to seek approval to market MM-120, MM-402 and other current or future 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 current product candidates or our future 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 current product candidates or future product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our current product candidates or future product candidates and may be affected by existing and future healthcare reform measures.

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 or any future product candidates as substitutable and only offer to reimburse patients for the less expensive product candidates. Even if we show improved efficacy or improved convenience of administration with our current product candidates or any future 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 current product candidates or any future 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 current product candidates or any future 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.

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 or any future 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 or any future 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 or any future product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any product candidates for which we obtain marketing approval.

EU drug marketing regulation may materially affect our ability to market and receive coverage for our product candidates in the EU Member States. 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 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. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost- effectiveness of our product candidates or any of our future 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. This will most likely change in 2025. 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 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 or any of our future product candidates in those countries would be negatively affected.

Moreover, increasing efforts by governmental and third-party payors in the EU, 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 or any future 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 current product candidates or any future 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. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and proposed 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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. 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 MM-120, MM-402 or any other current or future 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 and any future 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 study or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations, or 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 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 founders 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 that could be the basis for products that challenge the discovery research capabilities of MM-120, MM-402 or other current and future products 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 its product candidates. The success of our competitors and their product candidates relative to our technological capabilities and competitiveness could have a material adverse effect on the future preclinical studies and clinical trials of our product candidates, including its ability to obtain the necessary regulatory approvals for the conduct of such clinical trials. This may further negatively impact our ability to generate future product development programs using MM-120, MM-402 or other current or future product candidates or research compounds.

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, 2022, we had 48 full-time employees, including 27 employees engaged in research and development, 6 in digital development and 15 in general and administrative positions. 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 clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for MM-120, MM-402 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 MM-120, MM-402 or other current or future 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 MM-120, MM-402 or any other current or future 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 MM-120, MM-402 or other current or future 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 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.

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 parties service providers and technologies to operate critical business systems to process confidential and personal 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 (such as through theft or misuse), 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 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 breach of 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 goods and services. 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, including 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 security breach or other interruption. A security breach or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to information. A security breach 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 security breaches. 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. 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 security beach 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 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 security breaches. 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 security breach or are perceived to have experienced a security breach, we may experience adverse consequences. These consequences may include: government 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; and other similar harms. Security breaches 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.

Our operations are vulnerable to interruption by fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, fire, earthquake, power loss, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for any actual and catastrophic losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

If we are not able to establish, maintain and enhance our reputation and brand recognition, our business, financial condition and results of operations will be harmed.

We believe that establishing, maintaining and enhancing our reputation and brand recognition is critical to our relationships with existing and future healthcare practitioners, patients and collaborators. The promotion of our brand may require it to make substantial investments and we anticipate that, as our market becomes increasingly competitive, these marketing initiatives may become increasingly difficult and expensive. Brand promotion and marketing activities may not be successful or yield increased revenue, and to the extent that these activities yield increased revenue, the increased revenue may not offset the expenses that we incur, and our business, financial condition and results of operations could be harmed. In addition, any factor that diminishes our reputation or that of its management, including failing to meet the expectations of its network of healthcare practitioners, patients and collaborators, could harm its reputation and brand and make it substantially more difficult for us to attract new healthcare practitioners, patients and collaborators. If we do not successfully establish, maintain and enhance our reputation and brand recognition, its business may not grow and we could

lose its relationships with healthcare practitioners, patients and collaborators, which would harm our business, financial condition and results of operations.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and Canada 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, 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 or Canada;
- 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.

The exit of the UK from the EU, commonly referred to as "Brexit" could lead to further regulatory divergence and require us to incur additional expenses in order to develop, manufacture, and commercialize our products and services.

Following the result of a referendum in 2016, the UK left the EU on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020 (the "Transition Period"), during which EU rules continued to apply. The UK and the EU have signed a EU-UK Trade and Cooperation Agreement, or TCA, which entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate in the future. However, there are still many uncertainties and related positions regarding the conduct of clinical trials, the regulation of medicinal products and medical devices change frequently and continuously.

Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK.

Risks related to our intellectual property

If we infringe or are alleged to infringe the 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.

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office ("USPTO"), and Canadian Intellectual Property Office ("CIPO"), and corresponding foreign patent offices. Numerous U.S. and Canadian 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 may be subject to claims of infringement of the patent rights of third parties.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other 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. We have conducted patent searches for third-party patents with respect to our lead product candidates, and are not aware of third-party patent families with claims that, if valid and enforceable, could be construed to cover such product candidates or their respective methods of manufacture or use. We cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and Canada and abroad that is relevant or necessary to the commercialization 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. Moreover, we may face claims from non-practicing third-party entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, the scope of patent claims is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the asserted patent claims or that the claims are invalid and/or unenforceable, and we may not be successful.

Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. In proceedings before courts in the E.U., the burden of proving invalidity of a patent also usually rests on the party alleging invalidity. Even if we are successful in litigation, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could harm our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

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 likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary

damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

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 current or future 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 E.U. states (including Switzerland) 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.

So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from a U.S. application with an effective filing date prior to June 8, 1995 that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may be issued to our competitors covering our product candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and/or commercialization of a product candidate.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a candidate into the U.S. market.

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 any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States, Canada 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.

Our 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 any future patents, which could be expensive, time-consuming and unsuccessful.

We have issued patents and when and if we do obtain additional issued patents, we may discover that competitors are infringing these patents. Expensive and time-consuming litigation may be required to enforce our patents. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is 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 or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or CIPO or made a misleading statement during prosecution. 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.

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 any litigation we initiate to enforce our patents. 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 a negative impact on the market price of our securities. 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 and members on our board of directors who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact 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.

In addition, while we typically 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 rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in our successful development and

commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States, Canada 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, Canada and abroad related to our products that are important to our business. This 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.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the 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, Canada or in other foreign countries for many reasons. 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. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. 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.

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.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. 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. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products from using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

In addition to our issued patents, we have patent applications in the United States and other jurisdictions, which are currently pending, directed to various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents that may be issued to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents.

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.

We have filed patent applications directed to our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the patents covering lysergide, MDMA and 18-MC have expired. We have developed our own proprietary formulations or manufacturing methods for these products that we believe are not covered by valid claims of third-party patents, and we have filed patent applications directed to our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third-party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to MM-120, MM-402, MM-110 or other product candidates would cover the formulations of any competitors. We have patents and patent applications directed to aspects of our downstream manufacturing processes for various biosimilars, including MM-120. In contrast to our patent applications directed to formulations of MM-120, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third-party patents. As in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties.

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.

The USPTO, CIPO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. 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. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

Filing, prosecuting, defending and enforcing patents 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 and Canada can be less extensive than those in the United States and Canada. 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 or federal and provincial laws in Canada. Further, licensing partners may choose not to file patent 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 and Canada or importing products made using our inventions into the United States, Canada or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States or Canada. 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 could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act (the "America Invents Act"), signed into law on September 16, 2011.

As of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the America Invents Act. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO via procedures including post-grant and inter partes review. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a patent invalidated in a Patent Office post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could harm our business and financial condition.

Further, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I); BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., (Myriad II); and Promega Corp. v. Life Technologies Corp. have narrowed the scope of patent protection available in certain circumstances and weakened 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 future actions by the United States Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents that we might obtain in the future.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

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 expect 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 a party to research and license collaborations, including an exclusive worldwide license agreements with University Hospital Basel, pertaining to lysergide and other research products. 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.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property through licenses from third parties, including University Hospital Basel and MindShift Compounds AG. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Risks related to our dependence on third parties

We rely on third parties to supply and manufacture the lysergide, R(-)-MDMA and other controlled substances incorporated in our product candidates and expect to continue to rely on third parties to supply and manufacture any future 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 current or future 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 MM-120 or any current or future 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 and production of any commercial supply, if our product candidates are approved. Currently, we engage with multiple different CDMOs for all activities relating to the development, manufacture and production of all components incorporated in our product candidates. Reliance on third-party providers, such as CDMOs, exposes us to more risk than if we were to manufacture our product candidates, or any current or future product candidates. We do not control the manufacturing processes of the CDMOs we contract with and are dependent on those third parties for the production of MM-120, MM-402 or any current or future product candidates in accordance with relevant regulations (such as the FDA's GLP, cGMPs or similar regulatory requirements outside the US) for the manufacture of drug substances, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Some of the suppliers currently engaged in the production process of MM-120, MM-402 or any of our other current or future product candidates, including our current supplier of API, have not in the past been subject to inspection by the FDA and/or national competent authorities of the EU Member States 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 MM-120, MM-402 or any other current or future product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of MM-120, MM-402, other Schedule I controlled substances or any future 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 MM-120, MM-402 or any other current or future 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 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 reply 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 provider 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 and clinical studies 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, the EMA, the MHRA 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, the national competent authorities of the EU Member States, the MHRA or 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 could significantly interrupt our manufacturing capability. We currently do not have disaster recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial 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 will 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 or any future 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, the EMA, the MHRA 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 or any future 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 any future product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates or any future 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 or any future product candidates. As a result, our results of operations and the commercial prospects for our product candidates or any future 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.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

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.

Collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate relying upon strategic collaborations for marketing and commercializing our existing product candidates, if approved, and we may rely even more on strategic collaborations for research and development of other of our product candidates or discoveries. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our research and development efforts and potential to generate revenue may be limited.

If we enter into research and development collaborations during the early phases of product development, success will in part depend on the performance of research collaborators. We will not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our research and development programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we successfully establish new collaborations, these relationships may never result in the successful development or

commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for any future product candidate.

We may invest in pre-revenue companies which may not be able to meet anticipated revenue targets in the future.

We have made and may in the future make investments in companies with no significant sources of operating cash flow and no revenue from operations. Our investments in such companies will be subject to risks and uncertainties that new companies with no operating history may face. In particular, there is a risk that our investment in these pre-revenue companies will not be able to meet anticipated revenue targets or will generate no revenue at all, or such underperforming pre-revenue companies may fail, which could have a material adverse effect on our business, prospects, revenue, results of operation and financial condition.

Risks related to the securities markets and ownership of our common shares

We do not know whether an active, liquid and orderly trading market will continue for our common shares or what the market price of our common shares will be and as a result it may be difficult for you to sell your common shares.

Our securities commenced trading in Canada on the NEO Exchange in March 2020 and on the Nasdaq Capital Market in April 2021, but we can provide no assurance that we will be able to sustain an active trading market for our securities. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling our common shares and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our common shares as consideration.

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 periodic 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, Canada 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 3, 2022 to December 30, 2022, the closing price of our common shares on the Nasdaq Capital Market ranged from as low as $2.14 to as high as $22.80 and on the NEO Exchange ranged from as low as CAD $2.90 to as high as CAD $28.20 and daily trading volume ranged from approximately 47,500 to 15,471,720 shares on the Nasdaq Capital Market and daily trading volume ranged from approximately 3,341 to 533,431 shares on the NEO Exchange. 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.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our share price and trading volume could decline.

The trading market for our common shares is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We currently have research coverage from a limited number of securities or industry analysts. We do not have control over these analysts. There can be no assurance that analysts will continue to cover us, or provide favorable coverage. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our share performance or our market, or if our operating results fail to meet the expectations of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

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 any future 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 current product candidates and any future 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 MM-120, MM-402 and any of our other current or future 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 MM-120, MM-402 and any of our other current or future 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 MM-120, MM-402 or any of our other current or future product candidates;
- the level of demand for MM-120, MM-402 and any of our other current or future 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 MM-120, MM-402 and any of our other current or future product candidates;
- our ability to commercialize MM-120, MM-402 and any of our other current or future 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.

If we fail to meet all applicable Nasdaq 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.

On May 27, 2022, we received a letter from the staff of Nasdaq, notifying us that, for the previous 30 consecutive business days, the bid price for our common shares had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Global Select Market under Nasdaq Listing Rule 5550(a)(2). Our Board approved a reverse split of our common shares on a 15-for-1 basis, which was effected on August 26, 2022 (the "August Share Split") and which brought the bid price of our common shares above the minimum bid price requirement under the Nasdaq Listing Rules. On September 13, 2022, following the completion of the August Share Split, we received a notice from the Nasdaq Listing Qualifications Office indicating that we had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2).

There can be no assurance that we will maintain compliance with the requirements for listing our common shares on Nasdaq.

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.

A return on our securities is not guaranteed.

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

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 completion of our initial listing in the United States.

Notwithstanding the above, we are also currently a "smaller reporting company," meaning that we had a public float of less than $250.0 million 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; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; are not required to conduct say-on-pay and frequency votes; 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 not being required to comply with the auditor attestation requirements of Section 404 and 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.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to related compliance initiatives. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Canadian securities laws and regulations, Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, Nasdaq, Canadian securities regulators and the NEO Exchange. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage, particularly in light of recent cost increases related to coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of internal controls over financial reporting in this Annual Report, and once we cease to be an emerging growth company, we may be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve and maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and refine and revise a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue

steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. In addition, when we transitioned from a foreign private issuer to a domestic issuer, we were required to report our financials in our Annual Report on Form 10-K for the year ended December 31, 2021 under US GAAP rather than the International Financial Reporting Standards for the first time, which was complex and required significant investment of time of members of our management team. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal controls over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of shares of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal controls over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of shares of our common shares to decline.

In connection with the preparation of our consolidated financial statements as of and for the fiscal year ended December 31, 2021, a material weakness was identified in our internal controls over financial reporting in connection with our $5.0 million pledge in 2020 to an academic research institution to support a psychedelic research and training program. The pledge amount was and is payable by us in quarterly contributions over a five-year period to align with development and progress of the program. The deficiency identified was failing to accrue the $3.2 million liability at the time the pledge was committed to in 2020 notwithstanding the five-year quarterly payment schedule. To address this instance of a material weakness, we have taken steps to improve the design and operating effectiveness of our internal controls over financial reporting and such event has been remediated.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

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 this prospectus supplement, the accompanying prospectus or any applicable free writing prospectus filed with

the SEC 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. Beginning in August 2022, we received letters from a group of our shareholders that suggested certain governance and strategic changes, and have engaged in discussions with these and other shareholders from time to time. Securities litigation and shareholder activism, including potential proxy contests, could result in substantial costs and divert management's and the 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.

We do not intend to pay dividends on our common shares so any returns will be limited to the value of our common shares.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to any appreciation in the value of their shares. The payment of dividends in the future will be dependent on its earnings and financial condition in addition to such other factors as our Board considers appropriate. There is no present intention by our Board to pay dividends on its common shares.

We have broad discretion in the use of our cash, cash equivalents and short-term investments and may use them in ways in which you do not agree or in ways that do not increase the value of your investment.

Our management has broad discretion in the application of our cash, cash equivalents and short-term investments, and could spend these funds in ways that do not improve our results of operations or enhance the value of our Common Shares. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our Common Shares to decline and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents and short-term investments, in a manner that does not produce income or that loses value.

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.

Our articles contain provisions that establish 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.

The material differences between the BCBCA as compared to the Delaware General Corporation Law (the "DGCL"), which may be of most interest to shareholders include the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions, amendments to our articles) the BCBCA generally requires two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote of shareholders for similar material corporate transactions; (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.

Our financial statements are prepared according to U.S. GAAP and are no longer prepared under IFRS

Since our 2021 Annual Form 10-K filed on March 28, 2022, our consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") where 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"). Historical filings of our consolidated interim period and full year financial statements were previously prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") and may be subject to auditing and independence standards that may not be comparable to financial statements prepared according to U.S. GAAP. Although generally similar in principle, U.S. GAAP includes specific disclosure requirements that are not explicitly required in IFRS. Therefore, disclosures provided under IFRS and U.S. GAAP may differ depending on the nature of the risks and uncertainties associated with the underlying transaction. As a result, comparing our operating results across these varying periods may not be meaningful.

General risk factors

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the U.S. dollar, the Canadian dollar, the pound sterling and the euro. Our reporting currency is denominated in U.S. dollars and our functional currency is the Canadian dollar (except that the functional currency of our U.S. subsidiaries is the U.S. dollar) and the majority of our operating expenses are paid in U.S. dollars. We also regularly acquire services, consumables and materials in U.S. dollars, the Canadian dollar pound sterling and the euro. Further potential future revenue may be derived from abroad. As a result, our business and the price of our common shares may be affected by fluctuations in foreign exchange rates which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

In addition, the possible abandonment of the euro by one or more members of the EU, could materially affect our business in the future. Despite measures taken by the EU to provide funding to certain EU Member States in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more EU Member States, or in more extreme circumstances, the dissolution of the EU. The effects on our business of a potential dissolution of the EU, the exit of one or more EU Member States from the EU or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

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, 2022, we had available U.S. federal NOL carryforwards of $98.1 million which can be carried forward indefinitely. We also have available state NOL carryforwards of approximately $19.8 million as of December 31, 2022, of which $0.2 million can be carried forward indefinitely and $19.6 million expire beginning December 31, 2028 and are subject to limitation on use.

In addition, under Sections 382 and 383 of 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-change NOLs and certain other pre-change tax attributes to offset its post-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. Our ability to utilize our NOLs and certain other tax attributes could be limited by an "ownership change" as described above. 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 its 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 United States corporation for United States federal income tax purposes, pursuant to Section 7874(b) of the U.S. Internal Revenue Code of 1986 ("Code") , and the U.S. Treasury Regulations promulgated thereunder, notwithstanding that we have been incorporated under Canadian law, solely for U.S. federal income tax purposes, we will be classified as a U.S. domestic corporation. 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, while 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 USRPHC) will be subject to U.S. tax. Dividends on the common shares may be subject to Canadian or United States withholding tax. It is currently not anticipated that we will pay any dividends on the common shares in the foreseeable future.

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 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 tax 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 United States 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 United States federal income tax purposes regardless of its source; or
- a trust (A) the administration of which is subject to the primary supervision of a United States 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 United States person.

As a U.S. domestic corporation for U.S. federal income tax purposes, the taxation of our non-U.S. Holders upon a disposition of common shares generally depends on whether we classified as a USRPHC for U.S. federal income tax purposes. 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 under Section 280E of the Code.

Section 280E of the Code prohibits businesses from deducting certain expenses associated with trafficking-controlled substances (within the meaning of Schedule I and II of the CSA). The IRS has invoked Section 280E of the Code in tax audits against various businesses in the United States that are permitted under applicable state laws. Although the IRS issued a clarification allowing 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 permissible deductions. As a result, we will have an effective tax rate in the U.S. significantly higher than the rate typically applicable to U.S. corporations. While there are currently several pending cases before various U.S. administrative and federal courts challenging these restrictions, there can be no assurance that these courts will issue an interpretation of Section 280E of the Code favorable to our businesses.

Changes and uncertainties in the tax system in the countries in which we have operations could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We conduct business globally and file income tax returns in multiple jurisdictions. Our consolidated effective income tax rate could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organisation for Economic Co-Operation and Development's ("OECD"), Base Erosion and Profit Shifting ("BEPS"), Project, the European Commission's state aid investigations and other initiatives); the practices of tax authorities in jurisdictions in which we operate; the resolution of issues arising from tax audits or examinations and any related interest or penalties. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could increase the estimated tax liability that we have expensed to date and paid or accrued on our balance sheets, and otherwise affect our financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, Her Majesty's Revenue & Customs, the IRS, the Canada Revenue Agency or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer

pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. If we are assessed with additional taxes, this may result in a material adverse effect on our results of operations and/or financial condition.

A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable, or result in other liabilities.

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

Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic or political disruption such as the war between Ukraine and Russia could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

We or the third parties upon whom we depend on may be adversely affected by unplanned natural disasters, as well as occurrences of civil unrest, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our current business operations are conducted in our offices in Canada and New York in the U.S. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents, including events of civil unrest that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or any future product candidates or interruption of our business operations. Such unplanned natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot ensure that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

Item 1B. Unresolved Staff Comments.

None.

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. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information for Our Common Shares

Our common shares are publicly traded on the Nasdaq Capital Market under the symbol "MNMD" and on the NEO Exchange under the symbol "MMED". Prior to listing on the respective exchanges, there was no public trading market for our common shares.

Holders of Record

As of December 31, 2022, there were approximately 84 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 of directors 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 "Cautionary 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. References to "CAD$" are to Canadian dollars.

Overview

We are a clinical stage 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 that unlock new opportunities to improve patient outcomes. We are 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 MM-120 and MM-402, our lead product candidates.

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

On February 26, 2021, we acquired 100% of the issued and outstanding shares of HealthMode Inc. ("HealthMode"), a digital medicine and therapeutics company that used artificial intelligence enabled digital measurement to increase the precision and speed of clinical research and patient monitoring. The acquisition enabled us to build our digital medicine division. We plan to utilize these technologies in our clinical trials to enhance the quality of the data that is collected during our clinical trials.

Since inception, we have incurred losses while advancing the research and development of our products and processes. Our net losses were $56.8 million for the year ended December 31, 2022 and $93.0 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $194.5 million and cash and cash equivalents of $142.1 million.

During the period ended December 31, 2022, we continued to enhance the resources required to build our pipeline of opportunities. This included adding personnel and contract resources and ramping up the non-clinical aspects of our activities. In addition, considerable effort was directed towards employing a successful financing strategy.

Global Economic Conditions

Worldwide economic conditions remain uncertain and we continue to monitor the impact of macroeconomic conditions, including those related to the COVID-19 pandemic, the Russia-Ukraine war and rising inflation rates.

Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the Russia-Ukraine war, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Additionally, the general consensus among economists suggests a higher recession risk may continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. Furthermore, such economic conditions have produced downward pressure on share prices. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19 and the ongoing conflict between Russia and Ukraine, and employee availability and wage increases, which may result in additional stress on our working capital resources.

August 2022 Reverse Share Split

As previously disclosed, on May 27, 2022 we received a letter from Nasdaq's Listing Qualifications Department notifying us that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price for our listed securities was less than $1.00

for the previous 30 consecutive business days. We had a period of 180 calendar days, or until November 23, 2022, to regain compliance with the rule referred to in this paragraph.

Our Board of Directors approved a reverse share split of our common shares on a 15-for-1 basis, which was effected on August 26, 2022 and which brought the bid price of our common shares above the minimum bid price requirement under the Nasdaq Listing Rules. No fractional common shares were issued as a result of the August Share Split. Each fractional common share remaining upon the August Share Split that was less than 1/2 of a common share was cancelled and each fractional common share that was at least 1/2 of a common share was changed to one whole common share. The August Share Split affected all common shares outstanding immediately prior to the effective time of the August Share Split, as well as the number of common shares available under our stock option plan and equity incentive plan. In addition, the August Share Split effected a reduction in the number of common shares issuable upon exercise of stock options, vesting of Restricted Share Units and exercise of warrants outstanding immediately prior to the effectiveness of the August Share Split. All references to common shares, options to purchase common shares, share data, per share data, and related information contained in this report have been retrospectively adjusted to reflect the effect of the August Share Split for all periods presented.

On September 13, 2022, following the completion of the August Share Split, we received a notice from the Nasdaq Listing Qualifications Office indicating that we had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2).

Components of Operating Results

Operating Expenses

Research and Development

To date, our resources have focused primarily on the research and development of our product candidates MM-120, MM-402 and MM-110 (prior to when we paused development of MM-110 in the third quarter of 2022) and the commencement of related clinical activities, including funding data and study acquisitions and acquiring the materials required to supply our studies.

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, including:

- payroll, consulting and benefits expenses;
- licensing fees;
- manufacturing costs to produce clinical trial materials;
- clinical research costs associated with discovery, preclinical and clinical testing of our product candidates;
- data and study acquisition cost; 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 expense 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.

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, ADHD, ASD and other potential or future indications, including initiating additional and larger clinical trials.

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 services fees in connection with financing transactions, insurance expenses and allocated expenses.

We expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to support our research and development activities, grow our business and, if any of our product candidates receive marketing approval, commence commercialization activities. We also expect to increase the size of our administrative function and facility costs to support the growth of our business.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

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

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021	$ Change	% Change
Operating expenses:				
Research and development	$ 36,169	$ 34,789	$ 1,380	4%
General and administrative	30,162	59,065	(28,903)	-49%
Total operating expenses	66,331	93,854	(27,523)	-29%
Loss from operations	(66,331)	(93,854)	27,523	-29%
Other income/(expense):				
Interest income/(expense), net	1,495	(359)	1,854	*
Foreign exchange gain/(loss), net	195	(86)	281	*
Change in fair value of 2022 USD Financing Warrants	7,843	—	7,843	100%
Other income	2	106	(104)	-98%
Total other income/(expense), net	9,535	(339)	9,874	*
Loss before income taxes	(56,796)	(94,193)	37,397	-40%
Income tax benefit	—	(1,157)	1,157	-100%
Net loss	(56,796)	(93,036)	36,240	-39%
Other comprehensive gain:				
(Loss)/gain on foreign currency translation	(419)	762	(1,181)	-155%
Comprehensive loss	$ (57,215)	$ (92,274)	$ 35,059	-38%

** Represents a change greater than 300%*

Operating Expenses

Research and Development (in thousands):

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021	$ Change	% Change
External Costs				
MM-120 program	$ 7,448	$ 4,591	$ 2,857	62%
MM-110 program	1,419	6,999	(5,580)	-80%
External R&D collaborations	1,870	4,237	(2,367)	-56%
Preclinical and other programs	7,152	6,107	1,045	17%
Total external costs	17,889	21,934	(4,045)	-18%
Internal Costs	18,280	12,855	5,425	42%
Total research and development expenses	$ 36,169	$ 34,789	$ 1,380	4%

Research and development expenses increased by $1.4 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The increase was primarily due to increases of $2.9 million in expenses related to clinical research for MM-120 and $5.4 million in internal personnel costs as a result of increasing research and development capacities, offset by a decrease of $5.6 million in expenses related to our MM-110 program, and a decrease of $2.4 million of expenses in connection with various external R&D collaborations.

General and Administrative

General and administrative expenses decreased by $28.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The decrease was primarily due to a decrease of $27.4 million in non-cash stock-based compensation expenses primarily relating to the modification of stock option awards and RSUs recorded during the year ended December 31, 2021.

Other Income (Expense)

Interest Income/(Expense), Net

Interest income, net increased by $1.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. This was primarily due to interest earned on our cash and cash equivalents as a result of higher cash and cash equivalents and higher interest rates during the year ended December 31, 2022.

Foreign Exchange Gain/(Loss), Net

Foreign exchange gain increased by $0.3 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The increase was primarily due to favorable changes in foreign exchange rates during the year in relation to our 2022 USD Financing Warrants.

Other Income

Other income decreased by $0.1 million for the year ended December 31, 2022 compared to the year ended December 31, 2021 primarily due to a cessation of sales of branded merchandise.

Change in fair value of 2022 USD Financing Warrants

Revaluation gain on the 2022 USD Financing Warrants liability was $7.8 million for the year ended December 31, 2022. Gain on revaluation of the 2022 USD Financing Warrants liability consists of 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. No liability classified warrants were outstanding during the year ended December 31, 2021.

Income Tax Benefit

There was no income tax benefit or expense for the year ended December 31, 2022 compared to an income tax benefit of $1.2 million for the year ended December 31, 2021. Income tax benefit for the year ended December 31, 2021 was primarily due to the HealthMode acquisition.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have financed our operations primarily from the issuance of equity. 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 products. 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 products. There can be no assurance that we will be successful in continuing to finance our operations.

Our previous equity structure included Multiple Voting Shares, which had no par value and were eligible to be exchanged with Subordinate Voting Shares on a one-for-one-hundred basis, and Subordinate Voting Shares, which had no par value and were equivalent in rights to common shares. All equity financings described below, as applicable, have been revised to reflect the conversion of all outstanding Multiple Voting Shares and Subordinate Voting Shares to common shares, which was completed on June 30, 2022.

On January 7, 2021, we completed a bought deal financing resulting in the issuance of 1,395,333 units at a price per unit of CAD$66.00 ($52.05) for gross proceeds of $72.6 million. Each unit comprised one common share and one-half of one common share financing warrant (each whole warrant, a "January Warrant"). Each January Warrant entitles the holder thereof to purchase one common share at an exercise price of CAD$86.25 ($67.95) until January 7, 2024. Also, in connection with this transaction, we issued 83,720 compensation warrants to the underwriter.

On March 9, 2021, we completed a private placement bought deal financing resulting in the issuance of 400,000 units at a price per unit of CAD$48.75 ($38.55) for gross proceeds of $15.4 million. Each unit was comprised of one common share and one-half of one common share financing warrant (each whole warrant, a "March Warrant"). Each March Warrant entitles the holder thereof to purchase one common share at an exercise price of CAD$66.00 ($52.20) until March 9, 2024. Also, in connection with this transaction, we issued 24,000 compensation warrants to the underwriter.

On May 4, 2022, we filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, we may offer and sell securities having an aggregate public offering price of up to $200.0 million. In connection with the filing of the Registration Statement, we also entered into a sales agreement with Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc. as sales agents (together, the "Sales Agents"), pursuant to which we may issue and sell common shares for an aggregate offering price of up to $100.0 million under the ATM. Pursuant to the ATM, we will pay the Sales Agents a commission rate equal to 3.0% of the gross proceeds from the sale of any common shares. We are not obligated to make any sales of common shares under the ATM. As of December 31, 2022 we sold 2,311,652 common shares for net proceeds of $31.1 million under the ATM.

On September 30, 2022, we closed an underwritten public offering of 7,058,823 common shares and accompanying warrants to purchase 7,058,823 common shares (the "2022 USD Financing Warrants") at a combined offering price of $4.25 per common share, for net proceeds of $27.5 million. 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.

Our cash and cash equivalents and working capital as of December 31, 2022 were $142.1 million and $128.2 million, respectively. The increase in cash and cash equivalents was due mainly to the $58.6 million of net proceeds from financings mentioned above net of the cash used in operations of $50.1 million during the year ended December 31, 2022.

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 expect our current cash will be sufficient to fund our current operating plans into the first half of 2025. 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 to 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 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 current or future product candidates, if any.

Cash Flows

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Net cash used in operating activities	$ (50,139)	$ (45,824)
Net cash used in investing activities	—	(297)
Net cash provided by financing activities	59,051	98,824
Foreign exchange impact on cash	(309)	742
Net increase in cash	$ 8,603	$ 53,445

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2022 was $50.1 million, which consisted of a net loss of $56.8 million, partially offset by $10.5 million in non-cash charges and a net change of $3.8 million in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $13.7 million, and amortization of intangible assets of $3.2 million, partially offset by a change in fair value on the 2022 USD Financing Warrants liability of $7.8 million.

Cash used in operating activities for the year ended December 31, 2021 was $45.8 million, which consisted of a net loss of $93.0 million, partially offset by $45.3 million in non-cash charges and a net change of $1.9 million in our net operating assets and liabilities. The non-cash charges consisted of stock-based compensation of $42.7 million, and amortization of intangible assets of $2.6 million.

Cash flows from investing activities

Cash used in investing activities for the year ended December 31, 2021 was $0.3 million, which consisted of cash paid for the acquisition of HealthMode, net of cash acquired.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2022 was $59.0 million, which consisted of the net proceeds of $42.3 million from the issuance of common shares, net of issuance costs, proceeds of $17.7 million from the issuance of warrants, the proceeds of $0.7 million from exercise of warrants, and proceeds of $0.2 million from exercise of options, partially offset by $1.5 million of warrant issuance costs and $0.4 million of withholding taxes paid on vested RSUs.

Cash provided by financing activities for the year ended December 31, 2021 was $98.8 million, which consisted of the net proceeds of $81.9 million from the issuance of common shares and warrants, net of issuance costs, the net proceeds from exercise of warrants of $11.2 million, and proceeds of $5.7 million from exercise of options.

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 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 7 in the notes to our annual financial statements) are liability classified due to being denominated in USD and not the Company's functional currency. 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.

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 primary 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.

Fully Diluted Share Capital

The number of issued and outstanding common shares on a fully converted basis as of December 31, 2022 was as follows:

	Number of Common Share Equivalents
Common Shares	37,979,136
Stock Options	2,190,315
Restricted Stock Units	1,570,382
Compensation Warrants	125,890
Financing Warrants	1,286,282
2022 USD Financing Warrants	7,058,823
Total - December 31, 2022	50,210,828

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 sheet of Mind Medicine (MindMed) Inc. and subsidiaries (the Company) as of December 31, 2022, the related consolidated statement of operations and comprehensive loss, shareholders' equity, and cash flows for the year 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, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited the adjustments to the 2021 consolidated financial statements to retrospectively apply the reverse share split and conversion of all outstanding Multiple Voting Shares and Subordinate Voting Shares to Common Shares, as described in note 7. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2021 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2021 consolidated financial statements taken as a whole.

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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

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

San Diego, California
March 9, 2023

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Mind Medicine (MindMed) Inc. (the Company) as of December 31, 2021, the related consolidated statements of operations and comprehensive loss, shareholders' equity and cash flows for the year ended December 31, 2021, and the related notes, before the effects of the adjustments to retrospectively apply the reverse share split and conversion of all outstanding Multiple Voting Shares and Subordinate Voting Shares to Common Shares as described in note 7 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements, before the effects of the adjustments to retrospectively apply the reverse share split and conversion of all outstanding Multiple Voting Shares and Subordinate Voting Shares to Common Shares as described in note 7, present fairly, in all material respects, the financial position of the Company at December 31, 2021 and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We were not engaged to audit, review or apply any procedures to the adjustments to retrospectively apply the reverse share split and conversion of all outstanding Multiple Voting Shares and Subordinate Voting Shares described in note 7 and accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by other auditors.

Basis for Opinion

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

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

/s/ Ernst & Young LLP

Chartered Professional Accountants
Licensed Public Accountants

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

Toronto, Canada
March 28, 2022

Mind Medicine (MindMed) Inc.

Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 142,142	$ 133,539
Prepaid and other current assets	3,913	3,676
Total current assets	146,055	137,215
Goodwill	19,918	19,918
Intangible assets, net	3,689	6,869
Other non-current assets	331	—
Total assets	$ 169,993	$ 164,002
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,111	$ 4,178
Accrued expenses	5,877	6,230
2022 USD Financing Warrants	9,904	—
Total current liabilities	17,892	10,408
Other liabilities, long-term	1,184	1,930
Total liabilities	19,076	12,338
Commitments and contingencies (Note 11)		
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of December 31, 2022 and 2021; 37,979,136 and 28,126,414 issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	344,758	288,290
Accumulated other comprehensive income	627	1,046
Accumulated deficit	(194,468)	(137,672)
Total shareholders' equity	150,917	151,664
Total liabilities and shareholders' equity	$ 169,993	$ 164,002

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,	
	2022	2021
Operating expenses:		
Research and development	$ 36,169	$ 34,789
General and administrative	30,162	59,065
Total operating expenses	66,331	93,854
Loss from operations	(66,331)	(93,854)
Other income/(expense):		
Interest income/(expense), net	1,495	(359)
Foreign exchange gain/(loss), net	195	(86)
Change in fair value of 2022 USD Financing Warrants	7,843	—
Loss on revaluation of derivative liability	—	—
Other income	2	106
Total other income/(expense), net	9,535	(339)
Loss before income taxes	(56,796)	(94,193)
Income tax benefit	—	(1,157)
Net loss	(56,796)	(93,036)
Other comprehensive (loss)/gain:		
(Loss)/gain on foreign currency translation	(419)	762
Comprehensive loss	$ (57,215)	$ (92,274)
Net loss per common share, basic and diluted	$ (1.84)	$ (3.40)
Weighted-average common shares, basic and diluted (Note 2)	30,857,463	27,377,082

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					
	Shares	Amount	Additional Paid-In Capital	Accumulated OCI	Accumulated Deficit	Total
Balance, December 31, 2020	24,075,677	—	120,220	284	(44,636)	75,868
Issuance of common shares and warrants, net of share issuance costs	1,795,333	—	81,924	—	—	81,924
Issuance of common shares for vested director compensation	119,016	—	190	—	—	190
Share-based settlement payment	100,000	—	4,869	—	—	4,869
HealthMode acquisition	543,313	—	27,159	—	—	27,159
Exercise of warrants	541,838	—	11,178	—	—	11,178
Exercise of stock options	803,727	—	5,722	—	—	5,722
Vesting of restricted stock units	147,510	—	—	—	—	—
Stock-based compensation expense	—	—	37,028	—	—	37,028
Net loss and comprehensive loss	—	—	—	762	(93,036)	(92,274)
Balance, December 31, 2021	28,126,414	—	288,290	1,046	(137,672)	151,664
Issuance of common shares and warrants, net of share issuance costs	9,370,476	—	42,297	—	—	42,297
Exercise of warrants	76,021	—	708	—	—	708
Exercise of stock options	38,275	—	206	—	—	206
Settlement of restricted share unit awards	367,950	—	—	—	—	—
Withholding taxes paid on vested restricted share units	—	—	(407)	—	—	(407)
Stock-based compensation expense	—	—	13,664	—	—	13,664
Net loss and comprehensive loss	—	—	—	(419)	(56,796)	(57,215)
Balance, December 31, 2022	37,979,136	$ —	$ 344,758	$ 627	$ (194,468)	$ 150,917

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,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (56,796)	$ (93,036)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	13,707	42,716
Amortization of intangible assets	3,180	2,616
Unrealized foreign exchange	(148)	—
Non-cash lease expense	43	—
Issuance costs on 2022 USD Financing Warrants	1,500	—
Change in fair value of 2022 USD Financing Warrants	(7,843)	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	(260)	(2,163)
Other noncurrent assets	(180)	—
Accounts payable	(2,056)	1,282
Accrued expenses	(416)	4,631
Deferred tax liability	—	(1,157)
Contribution payable	(870)	(713)
Net cash used in operating activities	(50,139)	(45,824)
Cash flows from investing activities		
Acquisition, net of cash acquired	—	(297)
Net cash used in investing activities	—	(297)
Cash flows from financing activities		
Proceeds from issuance of common shares, net of issuance costs	42,297	81,924
Proceeds from issuance of 2022 USD Financing Warrants	17,747	—
Payment of 2022 USD Financing Warrants issuance costs	(1,500)	—
Proceeds from exercise of warrants	708	11,178
Proceeds from exercise of options	206	5,722
Withholding taxes paid on vested restricted stock units	(407)	—
Net cash provided by financing activities	59,051	98,824
Effect of exchange rate changes on cash	(309)	742
Net increase in cash and cash equivalents	8,603	53,445
Cash and cash equivalents, beginning of year	133,539	80,094
Cash and cash equivalents, end of year	$ 142,142	$ 133,539
Supplemental disclosures of non-cash financing activities:		
Right-of-use assets obtained in exchange of operating lease liabilities	194	—

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

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 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 MM-120 and MM-402, the Company's lead product candidates.

As of December 31, 2022, the Company had an accumulated deficit of $194.5 million. Through December 31, 2022, all the Company's financial support has primarily been provided by proceeds from the issuance of Common Shares and warrants to purchase Common Shares.

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 financial statements.

Global Economic Conditions

Worldwide economic conditions remain uncertain and the Company continues to monitor the impact of macroeconomic conditions, including those related to the COVID-19 pandemic, the Russia-Ukraine war and rising inflation rates.

Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the Russia-Ukraine war, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Additionally, the general consensus among economists suggests a higher recession risk may continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect the Company's operations. Furthermore, such economic conditions have produced downward pressure on share prices. Although the Company does not believe that inflation has had a material impact on its financial position or results of operations to date, the Company may experience increases in the near future (especially if inflation rates continue to rise) on its operating costs, including its labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19 and the ongoing conflict between Russia and Ukraine, and employee availability and wage increases, which may result in additional stress on its working capital resources.

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 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 an offering or such earlier time that it is no longer an EGC.

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").

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.

Foreign Currency

The Company's reporting currency is U.S. dollars. In 2019, the Company only operated MindMed US, a single US-based entity, which had a functional currency of the U.S. dollar. After the reverse takeover transaction in February 2020, the Company determined that the functional currency of the Company to be the U.S. dollar. During the fourth quarter of 2020, the Company determined that the there was a significant change in circumstances relating to the primary economic environment of the Company, which required a change in the entity's functional currency from the U.S. dollar to the Canadian dollar ("CAD"). This change in functional currency for the Company, was applied prospectively.

The local currency of the Company's foreign affiliates is generally their functional currency. Accordingly, the assets and liabilities of the foreign affiliates and the parent entity, are translated from their respective functional currency to U.S. dollars using fiscal year-end exchange rates, income and expense accounts are translated at the average rates in effect during the fiscal year and equity accounts are translated at historical rates. Transactions denominated in currencies other than the functional currency are remeasured to the functional currency at the exchange rate on the transaction date. Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured at period-end using the period-end exchange rate.

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 intangible assets, functional currency, and share-based awards and valuation of 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, 2022, the Company's cash equivalents primarily includes a U.S. government money market fund at a high-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-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, 2022, 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, 2022 and 2021.

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, 2022 and 2021.

Warrants

Compensation Warrants

Freestanding warrants for the purchase of Common Shares issued in conjunction with the Company's US offerings and various financing transactions as a form of compensation are classified as equity and recorded at fair value at the time of issuance. The Company accounted for these as transactions as issuance costs related to the underlying equity transactions.

Financing Warrants

Freestanding warrants for the purchase of Common Shares issued in conjunction with the Company's US offering and various financing transactions for the purchase of Common Shares are classified as equity and recorded at fair value at the time of issuance.

2022 USD Financing Warrants

The 2022 USD Financing Warrants (as defined below in Note 7) are liability classified due to being denominated in USD and not the Company's functional currency. 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.

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. Cash equivalents consist primarily of money market funds. The Company's accounts, at times, may exceed federally insured limits. The Company had cash equivalents of $131.7 million as of December 31, 2022, and no cash equivalents as of December 31, 2021.

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.

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 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. For preclinical studies, 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 expense primarily consists of payroll, including stock-based compensation, for executive management and administrative employees, including finance and accounting, legal, human resources and other offices supporting administrative functions, consulting and professional services fees, advisory and professional services fees in connection with financing transactions, insurance expenses, issuance costs related to warrants, and allocated expenses.

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:

	Years Ended December 31,	
	2022	2021
Numerator:		
Net loss attributable to common shareholders	$ (56,796)	$ (93,036)
Denominator:		
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	30,857,463	27,377,082
Net loss per share attributable to common shareholders, basic and diluted	$ (1.84)	$ (3.40)

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,	
	2022	2021
Options issued and outstanding under stock option plan	2,190,315	1,539,511
Unvested RSUs	1,522,793	644,481
Vested and unissued RSUs	47,589	52,852
Compensation Warrants	125,890	125,890
Financing Warrants	1,286,282	1,376,772
2022 USD Financing Warrants	7,058,823	—
Total	12,231,692	3,739,506

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 stock 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 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—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. The fair market value of one DDSU is equal to the volume weighted average trading price of a Common Share on the NEO Exchange for the five business days immediately preceding the valuation date. The Company revalues DDSUs on a quarterly basis. 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.

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 February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On April 8, 2020, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. The Company adopted this standard effective January 1, 2022, the adoption had no impact on the consolidated financial statements. The Company adopted the standard using the practical expedients allowing the Company to not reassess (i) whether any expired or existing contracts are or contain leases, (ii) the lease classification for any expired leases, and (iii) indirect costs for any existing leases. The Company has elected to not separate lease and non-lease components for any leases within its existing classes of assets, therefore the Company accounts for lease and non-lease components as a single lease component. The Company has also elected to not apply the recognition requirement to any leases within its existing classes of assets with a term of 12 months or less.

Recently Issued Accounting Pronouncements

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On April 8, 2020, the FASB has changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2023. The Company does not expect the impact of this standard on its financial position, results of operations, and cash flows to be material.

3. ACQUISITIONS

HealthMode Acquisition

On February 26, 2021 the Company acquired 100% of the issued and outstanding shares of HealthMode Inc. ("HealthMode"), a developer of technologies using Artificial Intelligence (AI)-enabled digital measurement to increase the precision and speed of clinical research and patient monitoring. The Company plans to utilize these technologies in its clinical trials to enhance the quality of the data that is collected during the Company's clinical trials.

The consideration paid for the acquisition of HealthMode was $27.6 million, and consisted of $0.5 million cash, 5,433 Multiple Voting Shares (equivalent to 543,313 Common Shares), valued at approximately $27.0 million based upon the closing price of the Company's Common Shares on the acquisition date, and $0.1 million in stock options (2,241 stock options), which are convertible into Common Shares of the Company. The Company incurred acquisition costs of $0.3 million in connection with the acquisition, primarily related to legal, accounting, and other professional services, which were recorded to general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss.

The Company recognized this transaction as a business combination. The Company recognized approximately $9.5 million of identifiable finite-lived intangible assets and $19.9 million of goodwill related to the acquisition of HealthMode. The identifiable finite-lived intangible assets are expected to be amortized over their useful lives which are estimated to be three years.

The following table sets forth the allocation of the purchase price to the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed, with the excess recorded to goodwill (in thousands):

Cash	$	178
Prepaid and other current assets		75
Property and equipment		15
Intangible assets (developed technology)		9,485
Goodwill		19,918
Total assets		**29,671**
Accounts payable and accrued expenses		880
Deferred tax liability		1,157
Total liabilities		**2,037**
Net assets acquired	**$**	**27,634**

Actual and pro forma results for this acquisition have not been presented as the financial impact to the Company's consolidated statement of operations is not material.

The goodwill is attributable to the value of the assembled workforce, and the related expertise and developed business function. Further, the acquisition is expected to allow the Company to streamline its product development processes. None of the goodwill is expected to be deductible for tax purposes.

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, 2022 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. The Company had no assets measured at fair value on a recurring basis as of December 31, 2021.

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents	$ 131,702	$ —	$ —	$ 131,702
Financial liabilities:				
Directors' Deferred Share Unit Liability	$ 124	$ —	$ —	$ 124
2022 USD Financing Warrant Liability	$ —	$ —	$ 9,904	$ 9,904

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Directors' Deferred Share Unit Liability	$ 509	$ —	$ —	$ 509

There were no transfers into or out of Level 1, Level 2, or Level 3 during the years ended December 31, 2022 and 2021.

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 are classified as Level 3 in the fair value hierarchy and are determined using the Black-Scholes option pricing model using the following assumptions:

	For the Year Ended December 31, 2022
Share price	$2.20 - $3.50
Expected volatility	96.04% - 97.08%
Risk-free rate	3.94% - 4.06%
Expected life	4.75 - 5.0 years

5. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

During the year ended December 31, 2022, the Company has made no additions to its outstanding goodwill. During 2022, the Company performed its annual goodwill impairment test and considered the decrease in its share price as well as other market factors as triggering events and determined a quantitative analysis was needed to be performed. As a result of the quantitative analysis, no impairment loss was recognized. No impairment charges have been recorded during the years ended December 31, 2022 and 2021.

Intangible assets, net

The following table summarizes the carrying value of the Company's intangible assets (in thousands):

		December 31, 2022		
	Useful Lives (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed Technology	3	$ 9,485	$ (5,796)	$ 3,689
Total intangible assets, net		$ 9,485	$ (5,796)	$ 3,689

		December 31, 2021		
	Useful Lives (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed Technology	3	$ 9,485	$ (2,616)	$ 6,869
Total intangible assets, net		$ 9,485	$ (2,616)	$ 6,869

Developed technology has a remaining useful life of 1.2 years. Amortization expense included in research and development expense was $3.2 million and $2.6 million for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the expected future amortization expense for finite-lived intangible assets was as follows (in thousands):

Year Ending December 31,	Amount
2023	$ 3,162
2024	527
Total	$ 3,689

6. ACCRUED EXPENSES

At December 31, 2022 and 2021, accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation	$ 3,198	$ 2,295
Professional services	436	2,313
Contribution payable	1,566	713
Accrued clinical and manufacturing costs	605	906
Lease liabilities	72	—
Other payables	—	3
Total accrued expenses	$ 5,877	$ 6,230

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, 2022, the Company had issued and outstanding 37,979,136 shares of Common Shares.

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 speak 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 any meeting of shareholders is two persons present at the meeting, each of whom is entitled to vote at the meeting, and who hold or represent by proxy in the aggregate not less than 5% of the outstanding shares of the Company entitled to vote at the meeting.

The Company's previous equity structure included Multiple Voting Shares, which had no par value and were eligible to be exchanged with Subordinate Voting Shares on a one-for-one-hundred basis, and Subordinate Voting Shares, which had no par value and were equivalent in rights to Common Shares. All share data shown in the accompanying consolidated financial statements and related notes has been retroactively revised to reflect the conversion of all outstanding Multiple Voting Shares and Subordinate Voting Shares to Common Shares as of December 31, 2022.

During the first quarter of 2022, holders of 301 Multiple Voting Shares exchanged their shares for 30,137 Subordinate Voting Shares on a one-for-one-hundred basis. These Subordinate Voting Shares were subsequently redesignated as Common Shares as of June 30, 2022.

August 2022 Reverse Share Split

The Company's Board of Directors (the "Board") approved a reverse split of the Company's Common Shares on a 15-for-1 basis (the "August Share Split"), which was effected on August 26, 2022, and which brought the bid price of the Company's Common Shares above the minimum bid price requirement under the Listing Rules of The Nasdaq Stock Market LLC ("Nasdaq"). No fractional Common Shares were issued as a result of the August Share Split. Each fractional Common Share that was remaining upon the August Share Split that was less than ½ of a Common Share was cancelled and each fractional Common Share that was at least ½ of a Common Share was changed to one whole Common Share. The August Share Split affected all Common Shares outstanding immediately prior to the effective time of the August Share Split, as well as the number of Common Shares available under the Company's stock option plan and equity incentive plan. In addition, the August Share Split effected a reduction in the number of Common Shares issuable upon exercise of stock options, vesting of Restricted Share Units and exercise of warrants outstanding immediately prior to the effectiveness of the August Share Split. All references to Common Shares, options to purchase Common Shares, share data, per share data, and related information contained in these financial statements have been retrospectively adjusted to reflect the effect of the August Share Split for all periods presented.

Common Shares Issued

2021 Equity Transactions

On January 7, 2021, the Company completed a bought deal financing resulting in the issuance of 1,395,333 units of the Company at a price per unit of CAD$66.00 ($52.05) for gross proceeds of $72.6 million. Each unit comprised one Common Share of the Company and one-half of one Common Share financing warrant (for a total of 697,667 warrants) (each whole warrant, a "January Warrant"). Each January Warrant entitles the holder thereof to purchase one Common Share at an exercise price of CAD$86.25 ($67.95) until January 7, 2024. Also, in connection with this transaction, the Company issued 83,720 compensation warrants to its underwriter (see Note 8). Total cash share issuance costs of $4.9 million were deducted from the gross proceeds.

On March 9, 2021, the Company completed a private placement bought deal financing resulting in the issuance of 400,000 units of the Company at a price per unit of CAD$48.75 ($38.55) for gross proceeds of $15.4 million. Each unit comprised one Common Share of the Company and one-half of one Common Share financing warrant (for a total of 200,000 warrants) (each whole warrant, a "March Warrant"). Each March Warrant entitles the holder thereof to purchase one Common Share at an exercise price of CAD$66.00 ($52.20) until March 9, 2024. Also, in connection with this transaction, the Company issued 24,000 compensation warrants to its underwriter (see Note 8). Total cash share issuance costs of $1.1 million were deducted from the gross proceeds.

During February and March 2021, the Company approved an officer of the Company to exchange 233,333 Common Shares for 2,333 Multiple Voting Shares. Between May and October holders of 44,132 Multiple Voting Shares exchanged their shares for 4,413,176 Common Shares.

On July 8, 2021, the Company issued 100,000 Common Shares to a holding company of its former CEO as part of a settlement agreement. The shares were valued at CAD$61.65 ($48.75) which was the value on the date that the shares were issued.

2022 Equity Transactions

On May 4, 2022, the Company filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to $200.0 million. In connection with the filing of the Registration Statement, the Company also entered into a sales agreement with Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc. as sales agents (together, the "Sales Agents"), pursuant to which the Company may issue and sell Common Shares for an aggregate offering price of up to $100.0 million under an at-the-market offering program (the "ATM"). Pursuant to the ATM, the Company will pay the Sales Agents a commission rate equal 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 ATM. As of December 31, 2022, the Company had sold 2,311,652 Common Shares for net proceeds of $31.1 million under the ATM.

On September 30, 2022, the Company closed an underwritten public offering of 7,058,823 Common Shares and accompanying warrants to purchase 7,058,823 Common Shares (the "2022 USD Financing Warrants") at a combined offering price of $4.25 per Common Share, for net proceeds of $27.5 million after deducting underwriting discounts and commissions and offering costs. 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.

Common Shares Reserved for Issuance

A summary of shares reserved for issuance as of December 31, 2022 is summarized below:

	December 31, 2022
Options issued and outstanding under stock option plan	2,190,315
Unvested RSUs	1,522,793
Vested and unissued RSUs	47,589
Compensation Warrants	125,890
Financing Warrants	1,286,282
2022 USD Financing Warrants	7,058,823
Shares available for grant under stock option plan	1,936,174
Total shares reserved for issuance	14,167,866

8. WARRANTS

The following table summarizes warrant activity for the year ended December 31, 2022.

	Expiration Date	Exercise Price (CAD$)	Outstanding as of December 31, 2021	Exercised	Expired	Outstanding as of December 31, 2022
December 11, 2020 compensation warrants	December 2023	$ 28.50	18,170	—	—	18,170
January 7, 2021 compensation warrants	January 2024	66.00	83,720	—	—	83,720
March 9, 2021 compensation warrants	March 2024	48.75	24,000	—	—	24,000
Total compensation warrants			125,890	—	—	125,890
May 26, 2020 financing warrants	May 2022	11.85	90,490	(76,021)	(14,469)	—
October 30, 2020 financing warrants	October 2023	21.00	122,510	—	—	122,510
December 11, 2020 financing warrants	December 2023	36.75	266,105	—	—	266,105
January 7, 2021 financing warrants	January 2024	86.25	697,667	—	—	697,667
March 9, 2021 financing warrants	March 2024	66.00	200,000	—	—	200,000
Total financing warrants			1,376,772	(76,021)	(14,469)	1,286,282

The following table summarizes warrant activity for the year ended December 31, 2021.

	Expiration Date	Exercise Price (CAD$)	Outstanding as of December 31, 2020	Issued	Exercised	Outstanding as of December 31, 2021
December 11, 2020 compensation warrants	December 2023	$ 28.50	72,680	—	(54,510)	18,170
January 7, 2021 compensation warrants	January 2024	66.00	—	83,720	—	83,720
March 9, 2021 compensation warrants	March 2024	48.75	—	24,000	—	24,000
Total compensation warrants			72,680	107,720	(54,510)	125,890
May 26, 2020 financing warrants	May 2022	11.85	189,811	—	(99,321)	90,490
October 30, 2020 financing warrants	October 2023	21.00	304,957	—	(182,447)	122,510
December 11, 2020 financing warrants	December 2023	36.75	444,410	27,255	(205,560)	266,105
January 7, 2021 financing warrants	January 2024	86.25	—	697,667	—	697,667
March 9, 2021 financing warrants	March 2024	66.00	—	200,000	—	200,000
Total financing warrants			939,178	924,922	(487,328)	1,376,772

The weighted average market fair value of shares purchased through warrant exercises during the years ended December 31, 2022 and 2021 was CAD$11.85 and CAD$68.25, respectively.

2022 USD Financing Warrants

On September 30, 2022, the Company closed an underwritten public offering of 7,058,823 Common Shares and accompanying warrants to purchase 7,058,823 Common Shares (see Note 7) at a combined offering price of $4.25 per Common Share, for net proceeds of $27.5 million after deducting underwriting discounts and commissions and offering costs. 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 outstanding liability classified 2022 USD Financing Warrants for the year ended December 31, 2022:

	2022 USD Financing Warrants	Weighted Average Exercise Price (USD$)
Balance at December 31, 2021	—	—
Issued	7,058,823	4.25
Exercised	—	—
Expired	—	—
Balance at December 31, 2022	7,058,823	4.25

The 2022 USD Financing Warrants are liability classified due to being denominated in USD and not the Company's functional currency. Accordingly, the 2022 USD Financing Warrants are recognized at fair value upon issuance and are adjusted to fair value at the end of each reporting period. Any change in fair value is recognized on the consolidated statements of operations. Issuance costs of $1.5 million related to warrants were expensed within general and administrative expense on the consolidated statements of operations.

	Year Ended December 31, 2022
Balance at December 31, 2021	$ —
Warrant liability at issuance	17,747
Change in fair value of the warrant liability	(7,843)
Balance at December 31, 2022	$ 9,904

9. STOCK-BASED COMPENSATION

Stock Incentive Plan

2020 Plan

On February 27, 2020, the Company adopted the MindMed Stock Option Plan (the "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 Plan sets out the framework for determining eligibility as well as the terms of any stock-based compensation granted. The 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 "Transaction") and is authorized to issue 15% of the Company's outstanding Common Shares under the terms of the Plan.

The fair value of options issued has been estimated using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Share price	CAD$3.47 - CAD$25.65	CAD$40.95 - CAD$63.15
Expected volatility	91.8% - 100.6%	91.8% - 101.3%
Risk-free rate	1.8% - 4.2%	0.3% - 0.8%
Expected life	2.5 - 6.1 years	2.7 - 3.6 years
Expected dividend yield	0%	0%

The following table summarizes the Company's stock option activity:

	Number of Options	Weighted Average Exercise Price (CAD$)	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (CAD$)
Options outstanding at December 31, 2021	1,539,511	$ 27.91	3.8	$ 13,610,348
Issued	990,015	18.96		
Exercised	(38,276)	6.58		539,982
Forfeited	(262,245)	27.88		
Expired	(38,690)	27.52		
Options outstanding at December 31, 2022	2,190,315	$ 24.29	4.1	$ 4,484
Options vested and exercisable at December 31, 2022	774,770	$ 25.76	3.1	$ 2,667

The weighted average grant date fair value of options granted during in the year ended December 31, 2022 was CAD$13.06. The aggregate fair value of options vested during the year ended December 31, 2022 was $9.7 million. The expense recognized related to options during the year ended December 31, 2022 was $6.7 million.

Restricted Share Units

The Company has adopted a Performance and Restricted Share Unit 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 plan sets out the framework for determining eligibility as well as the terms of any stock-based compensation granted. The plan was approved by the shareholders as part of the Arrangement. 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 (CAD$)
Balance at December 31, 2021	644,481	$ 45.11
Granted	1,391,275	11.86
Vested and unissued	(378,776)	38.54
Cancelled	(134,187)	33.17
Balance at December 31, 2022	1,522,793	$ 17.75

The fair market value of RSUs vested during the year ended December 31, 2022 was $4.0 million. The expense recognized related to RSUs during the year ended December 31, 2022 was $6.9 million.

Modification of Stock Options and RSUs

The Company modified the option awards and RSUs of certain employees and non-employees to accelerate the vesting and continue the vesting of 603,125 and 470,813 unvested options and 26,042 and 132,410 RSUs during 2022 and 2021, respectively, that were improbable of vesting as of the modification date. Under this type of modification, the original grant date fair value is remeasured, and compensation cost is recognized based on the fair value of the modified award, as measured on the modification date. For the years ended 2022 and 2021, the Company recognized $0.7 million and $21.9 million of incremental compensation cost, respectively, resulting from the modification in general and administrative expense in the consolidated statements of operations and comprehensive loss.

Directors' Deferred Share Unit Plan

2021 Plan

On April 16, 2021 the Company adopted the MindMed Director's Deferred Share Unit Plan ("DDSU Plan"). The DDSU Plan sets out a framework to grant non-executive directors DDSU's which are cash settled awards. The plan states that the fair market value of one DDSU shall be equal to the volume weighted average trading price of a Common Share on the NEO Exchange for the five business days immediately preceding the valuation date. The DDSU's 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, 2021	30,417
Issued	208,081
Settled	—
Cancelled	(24,699)
Balance at December 31, 2022	213,799

For the year ended December 31, 2022 stock-based compensation expense of a nominal amount 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. There were 71,478 DDSUs vested as of December 31, 2022. The liability associated with the outstanding vested DDSU's was $0.1 million as of December 31, 2022 and was recorded to accrued expenses in the accompanying consolidated balance sheets.

Director Share Compensation

On September 16, 2019, the Company entered into an agreement with an individual pursuant to which the individual agreed to: (i) join the Board, (ii) obtain a loan (the "Loan") of $0.5 million for the sole purpose of acquiring 333,333 Common Shares, and (iii) purchase 333,333 Common Shares for $0.5 million.

The Loan was accounted for as an option since the Company does not have full recourse to the outstanding loan balance. In the event the director ceases to be a member of the Board, the Common Shares would be tendered back to the Company without any payment being made. As a result, the Company has not recognized a loan receivable or the corresponding Common Shares as outstanding. The Company estimated the grant-date fair value of the Loan, which was recorded as share-based compensation expense over a two-year vesting period with a corresponding amount to additional paid-in capital. During the year ended December 31, 2021, the Company recognized $0.2 million in compensation expense in relation to this arrangement and issued 119,016 Common Shares to the director. During the year ended December 31, 2022, the Company did not recognize any compensation expense or issue any Common Shares to the director in relation to this arrangement.

Stock-based Compensation Expense

Stock-based compensation expense for all equity arrangements for the years ended December 31, 2022 and 2021 was as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 5,597	$ 7,174
General and administrative	8,110	35,542
Total share-based compensation expense	$ 13,707	$ 42,716

As of December 31, 2022, there was approximately $16.0 million of total unrecognized stock-based compensation expense, related to unvested options granted to employees under the Company's stock option plan that is expected to be recognized over a weighted average period of 2.6 years. As of December 31, 2022, there was approximately $18.7 million and of total unrecognized stock-based compensation expense, related to RSUs granted to employees under the Company's stock option plan that is expected to be recognized over a weighted average period of 2.7 years.

10. INCOME TAXES

The Components of the loss before income taxes were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Domestic	$ (61,763)	$ (44,573)
Foreign	4,967	(49,620)
Total	$ (56,796)	$ (94,193)

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,	
	2022	2021
Income tax at federal statutory rate	$ (11,926)	$ (19,781)
State income tax expense, net of federal tax effect	—	(16)
Nondeductible permanent items	224	46
Executive compensation	383	3,808
Warrant fair value adjustment	(3,240)	—
Capitalized research expenses	—	4,316
Net operating losses	—	(466)
Foreign rate differential	1,356	(12,617)
Adjustment to deferred taxes	10,742	(1,687)
Nonqualified stock option and performance award windfall upon exercise	1,732	2,461
Change in valuation allowance	729	22,779
	$ —	$ (1,157)

The difference between the statutory federal income tax rate and the Company's effective tax rate in 2022 and 2021 is primarily attributable to the change in valuation allowance, foreign rate differential, executive compensation, and capitalized research expenses.

The provision for (benefit from) income taxes is as follows (in thousands):

	December 31,	
	2022	2021
Current:		
Federal	$ —	$ —
State	—	2
Foreign	—	—
Total current	—	2
Deferred:		
Federal	—	(1,157)
State	—	(2)
Foreign	—	—
Total deferred	—	(1,159)
Total	$ —	$ (1,157)

The following table provides the effect of temporary differences that created deferred income taxes as of December 31, 2022 and 2021. 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,	
	2022	2021
Deferred tax assets:		
Reserves	$ 555	$ 47
Stock-based compensation	1,618	4,414
Share issuance costs	2,944	—
Net operating loss carryforward	25,312	31,932
Other assets	638	574
Intangible assets	442	898
Capitalized R&D	4,595	—
Lease liability	35	—
Valuation allowance	(36,107)	(35,808)
Net deferred income tax assets	32	2,057
Deferred tax liabilities:		
Right of use asset	(32)	—
Unrealized gain/loss	—	(620)
Intangible assets	—	(1,427)
Property and equipment	—	(10)
Other	—	—
Total deferred tax liabilities	(32)	(2,057)
Net deferred income tax liability	$ —	$ —

As of December 31, 2022 and 2021, 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, 2022 and 2021. Accordingly, a valuation allowance of $36.1 million has been recorded to offset this deferred tax asset. The valuation allowance increased by $0.3 million for the year ended December 31, 2022.

As of December 31, 2022, the Company has accumulated federal and state net operating loss ("NOL") carryforwards of $98.1 million and $19.8 million, respectively. The federal NOL carryforwards can be carried forward indefinitely, subject to 80% taxable income limitation. Of the $19.8 million of state NOL carryforwards, $0.2 million can be carried forward indefinitely and $19.6 million expire beginning December 31, 2028.

As of December 31, 2022 the Company had combined foreign net operating loss carryforwards available to reduce future taxable income of approximately $12.3 million, of which $0.1 million carryforward indefinitely, $9.6 million begin to expire in 2040, and $2.6 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 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, 2022 and 2021 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, 2022 and 2021, interest and penalties recognized were insignificant.

In December 2019, the FASB issued an ASU that simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. This ASU is effective for annual periods and interim periods for those annual periods beginning after December 15, 2020, with early adoption permitted. The Company adopted this standard effective January 1, 2021, the adoption had no impact on the consolidated financial statements.

The Tax Cuts and Jobs Act subjects a US 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, 2022 and 2021, 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 $31.6 million and $29.3 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. RELATED PARTY TRANSACTIONS

The Company had no related party transactions during the year ended December 31, 2022. The Company paid professional fees of approximately $1.1 million and corporate legal fees of approximately $0.8 million to entities controlled by a former director of the Company during the year ended December 31, 2021.

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, Chief Financial Officer, and Chief Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure. As of December 31, 2022, our Chief Executive Officer and Chief 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 Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2022.

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, 2022, 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, 2022 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.

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, 2022, 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, 2022, 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, 2022, 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, 2022, 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, 2022, 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.	8-K	3.1	June 30, 2022	001-40360
3.2*	Notice of Articles, Incorporated on July 26, 2010, as altered on June 30, 2022.				
4.1*	Description of Capital Stock of Mind Medicine (MindMed) Inc.				
4.2*	Form of Mind Medicine (MindMed) Inc. Common Share Certificate.				
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 Advisory Warrant to Purchase Common Shares of Mind Medicine (MINDMED) Inc.	10-K	4.4	March 28, 2022	001-40360
4.5	Form of Compensation Warrant to Purchase Common Shares of Mind Medicine (MINDMED) Inc.	10-K	4.5	March 28, 2022	001-40360
4.6	Form of Warrant Indenture by and between Mind Medicine (MindMed) Inc. and Odyssey Trust Company	10-K	4.6	March 28, 2022	001-40360
4.7	Form of 2022 USD Financing Warrant	8-K	4.1	September 28, 2022	001-40360
4.8*	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 October 30, 2020				
4.9*	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 December 11, 2020				
4.10*	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				

10.1#	Form of Director and Officer Indemnity Agreement.	10-K	10.1	March 28, 2022	001-40360
10.2*#	Mind Medicine (MindMed), Inc. Stock Option Plan.				
10.3#	Mind Medicine (MindMed), Inc. Performance and Restricted Share Unit Plan.	10-K	10.3	March 28, 2022	001-40360
10.4#	Form of Restricted Share Unit Grant Agreement to Performance and Restricted Share Unit Plan.	10-K	10.4	March 28, 2022	001-40360
10.5#	Non-Employee Director Compensation Policy	10-Q	10.2	August 11, 2022	001-40360
10.6#	Directors' Deferred Share Unit Plan	10-Q	10.3	August 11, 2022	001-40360
10.7#	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
10.8#	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
10.9#	Executive Employment Agreement dated as of November 9, 2022 between Mind Medicine (MindMed) Inc. and Dr. Miri Halperin Wernli	10-Q	10.3	November 10, 2022	001-40360
10.10#	Executive Employment Agreement dated as of November 9, 2022 between Mind Medicine (MindMed) Inc. and Schond Greenway	10-Q	10.4	November 10, 2022	001-40360
10.11#	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
10.12	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
10.13	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
10.14	Sales Agreement, dated as of May 3, 2022, by and among the Company, Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc.	S-3	1.2	May 4, 2022	001-40360
10.15*#	Mind Medicine (MindMed) Inc. Stock Option Plan (as amended and restated on March 7, 2023).				
10.16*#	Mind Medicine (MindMed) Inc. Performance and Restricted Share Unit Plan (as amended and restated on March 7, 2023).				
10.17*#	Form of Option Agreement to Mind Medicine (MindMed) Inc. Stock Option Plan.				
21.1	List of Subsidiaries of Mind Medicine (MindMed), Inc.	10-K	10.12	March 28, 2022	001-40360
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.				
23.2*	Consent of Ernst & Young 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.
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 Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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* 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.

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 9, 2023

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, Schond L. Greenway 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 9, 2023
/s/ Schond L. Greenway **Schond L. Greenway**	Chief Financial Officer (*Principal Financial Officer*)	March 9, 2023
/s/ Carrie F. Liao **Carrie F. Liao, CPA**	Chief Accounting Officer (*Principal Accounting Officer*)	March 9, 2023
/s/ Suzanne Bruhn **Suzanne Bruhn, PhD**	Director	March 9, 2023
/s/ Brigid A. Makes **Brigid A. Makes**	Director	March 9, 2023
/s/ Roger Crystal **Roger Crystal, MD**	Director	March 9, 2023
/s/ Andreas Krebs **Andreas Krebs**	Director	March 9, 2023
/s/ Carol Vallone **Carol Vallone**	Director	March 9, 2023