

Risk Factors Comparison 2025-03-06 to 2024-02-28 Form: 10-K

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The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report and those we may make from time to time. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our financial statements and related notes and the section titled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations, ” and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common shares could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common shares. Risks Related to Our Financial Position and Need for Additional Capital We have a limited operating history, have not ~~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 is MM120 **ODT**. ~~In December 2023 we announced statistically significant and clinically meaningful Phase 2b data for MM120 in GAD and in January 2024 we announced that our Phase 2a trial in ADHD did not meet its primary endpoint. We initiated~~ **anticipate initiation of our Phase 3 clinical program in GAD in December 2024 and we anticipate initiating our Phase 3 clinical program in MDD in the second first half of 2024-2025**. Additionally, in the third quarter of 2022, we paused development of MM110, 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 **and warrants to purchase our common shares**, and through our credit facility with K2 HealthVentures **LLC (“ K2HV ”)**. We incurred net losses of \$ ~~95-108~~ **7 million** and \$ ~~56-95~~ **8-7 million** for the years ended December 31, ~~2023-2024~~ and December 31, ~~2022-2023~~, respectively, and as of December 31, ~~2023-2024~~, we had an accumulated deficit of \$ ~~290-398~~ **2-9 million**. Our historical losses resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We intend to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance, market access, commercialization and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our product candidates are in various clinical, preclinical, discovery and research stages. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our expected losses, among other things, may continue to cause our working capital and shareholders’ equity to decrease. We anticipate that our expenses will increase substantially if and as we, among other things: • continue the clinical development of our product candidates and other preclinical programs in GAD, **MDD**, ASD and other potential or future indications, including initiating additional and larger clinical trials; • continue the training of healthcare practitioners who are qualified to deliver our product candidates in our clinical trials ; • ~~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 MM120 and MM402; • seek additional indications for our product candidates and discover and develop any future product candidates, including product candidates in our digital medicine pipeline; • seek regulatory approvals for any product candidates that successfully complete clinical trials; • experience heightened regulatory

scrutiny; • pursue necessary scheduling- related decisions to enable us to commercialize any future product candidates containing controlled substances for which we may obtain regulatory approval, including our MM120 and MM402 product candidates; • experience animal toxicology issues significant enough for the FDA or other regulatory agencies to disallow investigation in humans; • explore external business development opportunities through acquisitions, partnerships, co-development deals and / or licensing deals to add future product candidates and technologies to our portfolio; • obtain, maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent or other intellectual property infringement claims; • add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; • experience any delays or encounter any issues with respect to any of the above, including studies that impede further development with unfavorable results, ambiguous trial results, safety issues or other regulatory challenges; • expand our operations in the United States, ~~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, training a sufficient number of qualified healthcare practitioners to deliver our product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, rescheduling product candidates that are currently characterized as Schedule I controlled substances and establishing marketing capabilities. Even if any of the product candidates that we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the **FDA U. S. Food and Drug Administration**, or other comparable foreign authorities to perform studies or clinical trials in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of our product candidates, our expenses could increase beyond our current expectations and revenue could be further delayed. Even if we or any future collaborators do generate sales, we may never achieve, sustain or increase profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our common shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses, investors may not receive any return on their investment and may lose their entire investment. The net losses we incur may fluctuate significantly from quarter to quarter such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our common shares. The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility. In August 2023, we entered into a Loan and Security Agreement (the “ Loan Agreement ”) with ~~K2 Health Ventures LLC (“K2HV ”)~~, as administrative agent and Canadian collateral agent for lenders thereunder (K2HV, and any other lender from time to time, the “ Lenders ”), and Ankura Trust Company, LLC, as collateral trustee for the Lenders. At closing, we borrowed \$ 15. 0 million in the first tranche under the Loan Agreement, and **the second milestone- based tranche of \$ 10. 0 million was achieved and funded in the second quarter of 2024. We** may borrow an additional \$ **20-10**. 0 million based upon the achievement of certain time- based, clinical and regulatory milestones, and an additional \$ 15. 0 million upon our request, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders. Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets, other than certain intellectual property assets. The Loan Agreement includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our shareholders may consider beneficial. In addition, the Lenders could declare a default upon the occurrence of any event that it interprets could have material adverse effect, subject to the limitations specified in the Loan Agreement. Upon the occurrence and continuance of an event of default, the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Any declaration of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline. If we are liquidated, the rights of the Lenders to repayment would be senior to the rights of the holders of our common shares to receive any proceeds from the liquidation. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. We have never generated revenue and may never be profitable. We may never be able to develop or commercialize any marketable products or achieve profitability. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the acceptance of the product by physicians, payors and patients, the ability to obtain reimbursement and

whether we own the commercial rights for that territory. Our growth strategy depends on our ability to generate revenue. In addition, if the number of addressable patients is not as anticipated, the indication or intended use approved by regulatory authorities is narrower than expected, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, and pursue or continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates. Our business depends entirely on the successful discovery, development and commercialization of product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including:

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

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations. We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our research and drug development programs or future commercialization efforts. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our product candidates and advance our other programs. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA or other comparable foreign authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote MM120, MM402 or any other product candidate before we receive marketing approval from the FDA or other comparable foreign authorities. Accordingly, we will need to obtain substantial additional funding in order to continue our operations. As of December 31, 2023-2024, we had \$ 99-273 .7 million in cash and cash equivalents. Based on our current operating plan **and anticipated R & D**, we believe that we will be able to sufficiently fund our operations into 2026, if certain milestones, **we expect are achieved that unlock additional capital under our credit facility-cash runway to extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD**. Our estimate as to how long we expect our existing cash **to 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. Adequate additional financing may not be available to us on acceptable terms, or at all. Our future funding

requirements, both short- term and long- term, will depend on many factors, including: • the progress, timing and completion of preclinical testing and clinical trials for our product candidates; • the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to, including any delays as a result of animal toxicology issues or the need to conduct bioequivalence studies; • the outcome and timing of any scheduling- related decisions by the DEA, individual states, and comparable foreign authorities; • the number of potential future product candidates we identify and decide to develop, either internally through our research and development efforts or externally through acquisitions, licensing or other collaboration agreements; • the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our product candidates; • the costs of developing sales and marketing capabilities to target public and private HCPs and clinic networks in major markets; • the costs of training and certifying healthcare practitioners who are supporting or will support our clinical trials; • generating and collecting data and obtaining intellectual property; • the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringements raised by third parties; • the time and costs involved in obtaining regulatory approval for our product candidates, and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to our product candidates (such as MM120 and MM402) or any other product candidates; • selling and marketing activities undertaken in connection with the potential commercialization of our product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; • the amount of revenue, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and • the costs of operating as a public company. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or our product candidates, or we may be unable to take advantage of future business opportunities. ~~For example, in the third quarter of 2022, we paused the development of MM110 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 our product candidates on unfavorable terms. We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships, sales of assets and ~~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 Subject to certain rules of the Nasdaq Stock Market (" Nasdaq ")**, the Board has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. ~~For example, at December 31, 2022, we had an effective shelf registration statement 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, 2023, \$ 99. 8 million remained available for issuance under the shelf registration statement, of which \$ 59. 8 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 ATM market price for the common shares. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating and financing restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but may also limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships ~~or 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 product candidates. We cannot give any assurance that any of our product candidates will successfully complete clinical trials or receive regulatory approval, which is necessary before any product candidate can be commercialized. We currently have no products that are approved for commercial sale, and we may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to the development of our product candidates. Accordingly, our business currently depends on the successful regulatory approval of our product candidates and the commercialization of our product candidates if they receive regulatory approval. We cannot be certain that MM120, MM402, or any of our other product candidates will receive regulatory approval or that our product candidates will be successfully commercialized even if they receive regulatory approval. If we are required to discontinue development of our product candidates, or if MM120 or MM402 does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of our product candidates is, and will remain, subject to comprehensive regulation by the FDA, and other foreign regulatory authorities. Failure to obtain regulatory approval in the United States or other jurisdictions will prevent us from commercializing and marketing our product candidates in such jurisdictions. Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for our product candidates, any approval might contain significant limitations related to use, as well as restrictions for specified age groups, warnings, precautions, contraindications, and may be subject to additional monitoring and risk management plan requirements. In addition, we anticipate that any regulatory approval of our product candidates may include specific requirements or restrictions on the involvement or conduct of trained healthcare practitioners in the administration of our product candidates and we have not yet received any specific guidance from the FDA, or other regulatory bodies regarding such requirements or restrictions. Furthermore, even if we obtain regulatory approval for our product candidates, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, including securing availability of third-party treatment sites for the appropriate administration of our product candidates, securing adequate manufacturing, training and securing access to qualified healthcare practitioners, establishing a commercially viable pricing structure and obtaining coverage and adequate reimbursement from third- party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business. The success of our product candidates will depend on several factors, including the following:

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or clearance for conducting our clinical trials;
- successful patient enrollment in and completion of clinical trials;
- positive data from our clinical trials that support an acceptable risk- benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing and scaling up, either alone or with third- party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any product candidate is approved;
- **rescheduling of any Schedule I substance under the CSA and applicable state- controlled substance laws to Schedules II- V or equivalent categories at the state level, or out of the Schedules, and implementation of a REMS, if applicable;**
- entering into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection and / or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates benefits and uses, if approved, by patients, the medical community and third- party payors **, and overcoming potential public controversy regarding our product candidates containing Scheduled I substances**;
- maintaining a continued acceptable safety profile of our product candidates following approval;
- effectively competing with companies developing and commercializing other therapies in the indications which our product candidates targets;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors;
- enforcing and defending intellectual property rights and claims; and
- complying with laws and regulations, including laws and regulations applicable to controlled substances.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive marketing approvals for our product candidates, we may not be able to continue our operations. Our focus is on product candidates that are subject to controlled substance laws and regulations in the territories where the products are being developed and intended to be marketed, if approved, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations and our financial condition, both during clinical development and post approval, if any. In addition, the FDA and / or other regulatory bodies may require additional data, including with respect to abuse potential of our product candidates, before allowing us to commence a clinical trial or before approving any future marketing application we may submit. In the United States, lysergide and MDMA are listed by the DEA as “Controlled **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 **under the CSA**. 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. **For any product containing a Schedule I substance, such as lysergide or MDMA, to be available for commercial marketing in the United States, the substance or drug product containing the substance must be rescheduled under the CSA to Schedule II, III, IV or V or removed from the Schedules. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and special requirements for distribution, importation, and exportation.** Pharmaceutical products approved for **medicinal** use in the United States may be listed as Schedule II, III, IV or V, with

Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. ~~Schedule I~~ **Even if approved by FDA, prescribing and dispensing of a controlled substance is** subject to **restrictions** ~~the strictest controls under the CSA, with heightened restrictions including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II controlled substances~~ **drugs is further restricted**. For example, ~~they~~ **prescriptions for a Schedule II drug** 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 a Schedule I substance such as lysergide or MDMA to be available for commercial marketing in the United States, such Schedule I substance must be rescheduled, or the product containing such substance must be rescheduled, by the DEA to Schedule II, III, IV or V.~~ Commercial marketing in the United States will also require **state** scheduling- related legislative or administrative action. Scheduling determinations by the DEA are often dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while lysergide and MDMA are Schedule I controlled substances, products approved by the FDA for medical use in the United States that contain lysergide and / or MDMA must be descheduled or rescheduled to Schedules II- V, since approval by the FDA satisfies the “accepted medical use” requirement. If MM120 and MM402 receive FDA approval, HHS and the DEA must **complete a scheduling analysis and** make **a scheduling determination- determination and to** deschedule or place either the ~~substances- substance~~ or the ~~drug products- product~~ in a schedule other than Schedule I in order for them **to be able** to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the HHS’ s recommendation as to the appropriate schedule under the CSA. ~~To~~ **The reschedule rescheduling process requires** a substance or product, the DEA **must to** conduct notice - and - comment **rule-making rulemaking**, including issuing an interim final rule 90 days after the later of notice of FDA approval or DEA receipt of the HHS scheduling analysis and recommendation. Such action will be subject to public comment and requests for hearing. ~~There can be no assurance that the DEA will make a favorable scheduling decision.~~ **Even assuming categorization as a our product candidates are controlled in** Schedule II or lower ~~controlled substance (i. e., Schedule III, IV or V),~~ at the federal level, such substances or products may require **separate scheduling rescheduling or descheduling** determinations under state laws and regulations. If approved by the FDA, and if the finished dosage form of any of our product candidates is controlled ~~by the DEA~~ as a Schedule II, III, or IV controlled substance **under the CSA**, such product candidate’ s manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will continue to be subject to a significant degree of regulation by the DEA. ~~In addition, the scheduling process may take significantly longer than the 90- day timeframe set forth in the CSA, thereby delaying the launch of our product candidates in the United States.~~ In addition, product candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including: • DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of our product candidates. Furthermore, failure to maintain compliance with the CSA, particularly non- compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. • State- controlled substances laws. Individual U. S. states have also established controlled substance laws and regulations. Though state- controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates. While some states automatically schedule **(or reschedule)** a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law. • Clinical trials. Because our product candidates fall into categories of substances that are “controlled substances”, to conduct clinical trials on our product candidates in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our product candidates and to obtain our product candidates from our importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. We currently conduct our manufacturing or repackaging / relabeling of our product candidates or their active ingredients through our CDMOs in the United States and outside of the United States. • Importation. If our product candidates are approved and classified as Schedule II, III or IV substances, an importer can import them for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments / estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our product candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third- party comments to be submitted. It is always possible that adverse

comments may delay the grant of an importer registration. If our product candidates are approved and classified as Schedule II controlled substances, federal law may prohibit the import of the substance for commercial purposes. If our product candidates are listed as a Schedule II substances, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances, including our product candidates, have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if we are unable to import our product candidates or any of their drug substances, our product candidates would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.

- Manufacture in the United States. If, we were to conduct manufacturing or repackaging / relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of our product candidates **if approved**, the active ingredient in the final dosage form is currently a Schedule I controlled substance and would be subject to such quotas as these substances could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredient in MM120, MM402, or any other product candidate, may not be sufficient to complete clinical trials or meet **potential future** commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and / or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.
- Distribution in the United States. If our product candidates are scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute our product candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute our product candidates more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If our product candidates are Schedule II drugs, participants in our supply chain may have to maintain enhanced security with alarms and monitoring systems and they may be required to adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. In addition, our product candidates will likely be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial uptake. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products. Our product candidates are controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding controlled substances and psychedelics may negatively influence the success of our product candidates. Product candidates containing controlled substances **may have generate generated** public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. **Anti- psychedelic protests have historically occurred and may occur in the future and generate media coverage.** Opponents of these product candidates may seek **to prevent or** ~~restrictions~~ **restrict** on marketing **and or demand** 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. **In addition, Adverse adverse** publicity **related to** ~~from~~ misuse of lysergide or MDMA, or any other substance that underlies our product candidates or **fall into** ~~are part of~~ the same drug or chemical class, **which** may **be referred to as psychoactive or psychedelic drugs, may result from political or social opposition to controlled substances, misuse and abuse of controlled substances recreationally, or clinical trial conduct, including abuse by investigators.** ~~adversely~~ **Adverse publicity of not only our product candidates, but also any similar controlled substances, may affect** **our clinical trials, potential regulatory approval, and** the commercial success or market penetration achievable by our product candidates. **Anti- psychedelic protests have historically occurred** For example, Lykos Therapeutics, another company developing a drug product candidate containing MDMA, recently faced significant public scrutiny and adverse publicity following negative public statements and allegations about clinical trial conduct made by clinical trial participants. **Public controversy over the misuse or abuse potential of our or our competitor's product candidates may also harm our ability to recruit and retain clinical trial participants, negatively influence the recommendations of and an may FDA Advisory Committee, and / or result in the FDA requesting additional data related to the abuse potential of occur-- our product candidates, which could lead to delays in approval the future and generate media coverage** **increased research and development costs for our product candidates** **Even if our product candidates are approved by the FDA,** ~~Political~~ **political** pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our product candidates. We will be highly dependent upon consumer perceptions of the safety and quality of our product candidates if they are approved for commercial sale. We may face limited adoption if third- party treatment sites, HCPs, and patients are unwilling to try such a novel treatment **and press coverage may influence their willingness**. ~~There has been a~~ **In addition to the** history of negative media coverage regarding psychedelic substances, including lysergide and MDMA, ~~which~~ **recent and future public controversy related to clinical or recreational use of such substances,** may affect the public's perception of our product candidates, **which could adversely affect our business. We also could be adversely affected if any of our product candidates prove to be, or are asserted to be, harmful to patients, which could result in reputational harm**. In addition, lysergide elicits intense psychological experiences, and this could deter patients from **enrolling in clinical trials or** choosing this course of treatment ~~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 in other jurisdictions regarding the medical benefits, viability, safety, efficacy and dosing of psychedelic drugs remains **limited 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, **MDD**, ASD and other brain health disorders on which we focus our research efforts, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates. Drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals, which would mean that we would be unable to commercialize our product candidates on a timely basis or at all, which will adversely affect our business. Drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical and clinical trial process and we may never successfully progress a product candidate through clinical development. Furthermore, we may experience delays in completing our ongoing preclinical studies and clinical trials and initiating or completing additional preclinical studies or clinical trials. We may also experience numerous unforeseen events during preclinical and clinical development that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- delays in or failure to obtain regulatory approval to commence or modify a trial, including the imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an Investigational New Drug Application (“ IND ”), or amendment, clinical trial application (“ CTA ”), or amendment, or equivalent application or amendment, as a result of a finding that the trial presents unreasonable risk to clinical trial participants or a negative finding from an inspection of our clinical trial operations or study sites, or the occurrence of a suspected, unexpected serious adverse reaction (“ SUSAR ”), or serious adverse reaction (“ SAE ”), during our clinical trials or IITs, using our product candidates;
- delays or denial of a researcher registration to one or more research sites that will allow those sites to handle and dispense our product candidates and to obtain our product candidates from our importer;
- delays in or failure to reach agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or inability to raise sufficient capital to fund research and development of our product candidates;
- delays in or failure to obtain IRB, or ethics committee approval at each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post- treatment follow- up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- inability to identify or maintain a sufficient number of trial sites, many of which may be already engaged in other clinical trials, including some that may be for competing product candidates with the same indication;
- challenges related to conducting adequate and well- controlled clinical trials, including designing an appropriate comparator arm in studies given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results that are inconsistent with earlier results;
- availability of adequately trained HCPs and appropriate third- party clinical trial sites for our product candidates;
- sufficiency of any supporting digital services that may form part of the preparation, integration or long- term follow- up relating to any product candidate we develop;
- failure to contract for the manufacture of sufficient quantities of our product candidates for use in clinical trials in a timely manner;
- third- party actions claiming infringement by our investigational product candidates and other candidates or product candidates in clinical trials and obtaining injunctions interfering with our progress;
- safety or tolerability concerns which could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- unacceptable risk- benefit profile, unforeseen safety issues or adverse side effects or adverse events associated with a product candidate;
- failure of a product candidate to demonstrate any or enough of a benefit;
- methodological challenges associated with clinical research of psychotropic compounds that could hinder the interpretability or regulatory acceptability of clinical trial results, such as the effects of functional unblinding, expectation biases and protocols for patient support and monitoring during dosing sessions;
- changes in regulatory requirements, policies and guidelines;
- lower than anticipated retention rates of patients in clinical trials;
- our third- party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in our clinical trials related to public health crises like the COVID- 19 pandemic, due to factors such as a decrease in the willingness or availability of patients to enroll in our clinical trials and challenges in procuring sufficient supplies of the underlying therapeutic substance;
- the quality or stability of the underlying therapeutic substance falling below acceptable standards;
- regulatory requirements to change the formulation of a product candidate, which can require expensive, risky and time- consuming bioequivalence studies;
- business interruptions resulting from macroeconomic conditions, including inflation and rising interest rates, geo- political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, pandemics, or failures or significant downtime of our information technology systems resulting from cyber- attacks on such systems or otherwise; and

• changes in governmental regulations or administrative actions. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee (the “ DRC ”), or Data Safety Monitoring Board for such trial, as applicable, or by the FDA or other regulatory authorities or if the DEA registration of an investigator or site conducting the clinical trial is revoked. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including any SUSARs or SAEs which have in the past or may in the future occur in our trials or any IITs or other studies using lysergide, MDMA and any other substance that underlies our product candidates and those relating to the class to which lysergide, MDMA and other Schedule I controlled substances or any other product candidates belong, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of MM120, MM402 or any other product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate revenue from any such product candidates will be delayed. In addition, any delays in completing our clinical trials will likely increase our costs, slow down MM120, MM402 or any other product candidate development and approval process and jeopardize our ability to commence sales and generate revenue. Moreover, if we make changes to our product candidates, we may need to conduct additional bioequivalence studies to bridge such modified product candidates to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Significant preclinical and clinical trial delays could also allow our competitors to bring therapies to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early. Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of MM120, MM402, or any other product candidates that we may identify and pursue, which would prevent, delay or limit the scope of regulatory approval and commercialization. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication. To receive regulatory approval for commercial sale, a product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process ~~and, because our investigational product candidates are in an early stage of development, there~~ **There** is a high risk of failure and we may never succeed in developing marketable products. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our clinical trials will be successful. Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our clinical trials are inconclusive with respect to the efficacy of MM120, MM402 and any other product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with MM120, MM402 and any other product candidates, we may be delayed in obtaining marketing approval, or we may never obtain marketing approval. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of MM120, MM402 and any other product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. Even if our clinical trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do. Accordingly, more trials could be required before we submit any product candidates for approval. **In addition, the FDA or other foreign regulatory authorities may change their recommendations for clinical trial conduct, such as for assessing abuse potential, like hallucinations, or the use of psychological support or psychotherapy in combination with a product candidate, for our product candidates or their drug class through regulation, guidance, or informal communications at any time, especially as drug development in this area increases. Because clinical trials take a significant period of time, we cannot assure that our trial design will comply with future FDA recommendations for clinical investigations involving psychedelic drugs. We may have already initiated or completed our clinical trials, and may need to amend our study protocol or conduct additional clinical trials as a result, which could be costly and time-consuming, and may significantly delay or limit our ability to commercialize our product candidates. For example, the FDA issued a draft guidance in June 2023 outlining clinical considerations for psychedelic drugs. There can be no assurances that the FDA will not change its recommendations in a revised guidance or final guidance, or issue a new draft guidance that could affect our development programs.** To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that

other jurisdiction. Due to the inherent risk in the development of product substances, there is a significant likelihood that MM120, MM402 and any other product candidates will not successfully complete development and receive approval. Many other companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their product candidates. If we do not receive regulatory approvals for MM120, MM402 or any other product candidates, we may not be able to continue our operations. Even if regulatory approval is secured for MM120, MM402 or any other product candidate, the terms of such approval may limit the scope and use of a specific product candidate, which may also limit its commercial potential. **Changes in our formulation of MM120 could have a material adverse effect on our business, financial condition and results of operations. In August 2023, we entered into an exclusive licensing agreement with Catalent for its patented Zydis® orally ODT technology. Under the terms of the licensing agreement, Catalent granted us, among other things, access to its Zydis technology for the development of MM120. Zydis ODT is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water. In our Phase 2 clinical trials for MM120, we used a formulation of MM120 that did not include ODT technology. In 2024, we completed a pharmacokinetics (“PK”) bridging study to support the advancement of the MM120 ODT formulation into pivotal clinical trials, and we are using the MM120 ODT formulation in our Phase 3 clinical trials for GAD and MDD. This change in formulation could cause MM120 to perform differently, cause unforeseen side effects or affect the results of our Phase 3 clinical trials. This could delay completion of our Phase 3 clinical trials, require the conduct of additional bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs or delay or prevent the submission, or approval, of one or more NDAs for MM120. Such delays and costs could jeopardize our ability to, if approved, commercialize MM120 for GAD, MDD or other future indications, which could have a material adverse effect on our business, financial condition and results of operations.**

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. These data may not be sufficient to support regulatory submissions or approvals. From time to time, we may publish interim, topline or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of patients have been enrolled, but before completion of the trial. Similarly, we may report topline or preliminary results of primary and key secondary endpoints before the final trial results are completed. Interim, topline and preliminary data from our clinical trials may change as more patient data or analyses become available. Preliminary, topline or interim data from our clinical trials are not necessarily predictive of final results. Interim, topline and preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects. Further, others, including regulatory agencies **and independent organizations evaluating prescription drugs, such as the Institute for Clinical and Economic Review (“ICER”)**, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general, and regulatory agencies may request further data from us. In addition, you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize MM120, MM402 or any other product candidate, our business, operating results, prospects or financial condition may be harmed. We may not be able to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or similar regulatory authorities may not permit us to proceed in a timely manner, or at all. Prior to commencing clinical trials in the United States or other jurisdictions, we may be required to have an allowed IND (or equivalent) for each product candidate and to file additional INDs prior to initiating any additional clinical trials for such product candidates. We believe that the data from previous studies will support the filing of additional INDs to enable us to undertake additional clinical trials of our product candidate portfolio as planned. However, submission of an IND (or equivalent) may not result in the FDA (or equivalent authorities) allowing further clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials **(e. g., if the FDA places the trial on a clinical hold for safety reasons)**. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the future. Failure to submit or have effective INDs (or equivalent) and commence or continue clinical programs will significantly limit our ability to generate revenue. We may not achieve our publicly announced milestones according to schedule, or at all. From time to time, we may announce the timing of certain events that we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward- looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials, or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward- looking information or statements, whether as a result of new information, future events or otherwise,

except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business plan, financial condition or operating results and the trading price of our common shares. The regulatory approval process of the FDA and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for any product candidates, our business will be substantially harmed. We have not submitted a marketing authorization application to the FDA or other comparable foreign regulatory authority. Before obtaining regulatory approvals for the commercial sale of any product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities **to set approval policies and data requirements**. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. **Given the limited recent experience with clinical use of psychedelic drugs, it is likely the regulatory landscape will evolve, and could do so rapidly. We cannot guarantee that we will be able to or have the resources to adapt to changes regulatory requirements**. We have not obtained regulatory approval for any of our product candidates. It is possible that none of our product candidates will ever obtain regulatory approval. Any of our product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities or be precluded from commercial marketing for many reasons, including the following: • the FDA or other comparable foreign regulatory authorities may disagree with, question or request changes in the design or implementation of our clinical trials; • the FDA or other comparable foreign regulatory authorities may determine that MM120, MM402 or any other product candidates are not safe and effective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; • the results of clinical trials may not meet the level of statistical significance required by the FDA or other comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that our product candidate's clinical and other benefits outweigh its safety risks; • the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the FDA or other comparable foreign regulatory authorities may disagree with the design or implementation of our development programs, which may impact our ability to receive approvals for our product candidates; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a marketing authorization application with the FDA or other comparable foreign regulatory authority; • the FDA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; • the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and • the potential risk of our novel product candidates and delivery method, including the use of third-party clinical trial sites and healthcare practitioners. This lengthy approval process, **as well as the unpredictability of future clinical trial results, and the potential influence of public opinion** may result in our failing to obtain regulatory approval to market any product candidates, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process, **including the data required for regulatory approval**, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. If MM120, MM402 or any other product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process **(such as priority review in the US)**, this will prevent such product candidate from obtaining approval on a shortened time frame, or at all, resulting in increased expenses which would materially harm our business. In addition, even if we were to obtain approval, regulatory or pricing authorities may approve any product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios may have a negative impact on the commercial prospects for our product candidates and our business. Even if MM120, MM402 or any other product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any such product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If the FDA or a comparable foreign regulatory authority approves MM120, MM402 or any other product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product candidates and underlying product substance will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with ~~eGMPs~~ **cGMP**, and with good clinical practices ("GCPs"), for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such product candidates. Additionally, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U. S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA

and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Later discovery of previously unknown problems with any approved product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of MM120, MM402 or any other product candidates, withdrawal of such products from the market, or product recalls;
- untitled and warning letters, or holds on clinical trials;
- refusal by the FDA or other foreign regulatory body to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

In addition, any regulatory approvals that we receive for MM120, MM402 or any other product candidates may also be subject to limitations on the approved indicated uses for which the product candidates may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of such product candidates. For instance, we believe that MM120, if approved, would be subject to a Risk Evaluation and Mitigation Strategy ("REMS") program, under the applicable FDA regulations and similar risk mitigation programs in other jurisdictions. REMS programs are costly and time-consuming for providers to comply with, involving high administrative burden, which could delay or limit our ability to commercialize our product candidates. If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with our product candidates or our manufacture of an underlying product substance, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, ~~requiring~~ **require** us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product candidates may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations. Our product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of MM120, MM402 or any other product candidates or following approval, if any, we may need to abandon our development or commercialization of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences. Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials or result in clinical holds and could result in a more restrictive label, a requirement that we implement a REMS plan to ensure that the benefits of the product candidates outweigh its risks, or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. We or regulatory authorities may also learn of and take similar actions based on side effects related to MM120, MM402, any other product candidates, or similar compounds in studies not conducted by us, including in IITs or studies conducted by other sponsors, from spontaneous reports of use of these compounds outside of the clinical trial setting or from safety reports in literature. The results of future clinical trials may show that MM120, MM402 or any other product candidates cause undesirable or unacceptable side effects or even death. There can be no assurance that deaths or serious side effects will not occur, even in a clinical setting. In the event serious side effects occur, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of MM120, MM402 or any other product candidates for any or all targeted indications. Nonclinical toxicology studies may also delay or limit clinical development, for example, by limiting the dosing duration and dose interval in clinical trials. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, because of the high variability in how different individuals react to lysergide, certain patients may have negative experiences with the treatment that could subject us to liability or, if publicized, reputational harm. Any of these occurrences may harm our business, financial condition and prospects significantly. Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for MM120, MM402 or any other product candidates, we will have tested them in only a limited number of patients during our clinical trials. Clinical trials are by design based on a limited number of patients and of limited duration for exposure to the product candidates used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any such product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of MM120, MM402 or any other product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to such product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such trials may not be sufficient to identify when those events may occur. Additionally, if our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including the following:

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

change the labeling of the product candidate; • we may be subject to limitations on how we may promote the product candidate; • sales of the product candidates may decrease significantly; • we may be subject to litigation or product liability claims; and • our reputation may suffer. Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates. Even if we obtain FDA approval for MM120, MM402 or any other product candidates, we may never obtain approval to commercialize any such product candidates outside of the United States, which would limit our ability to realize their full market potential. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries or jurisdictions regarding safety and effectiveness. Clinical trials conducted in one country or jurisdiction may not be accepted by regulatory authorities in other countries or jurisdictions, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Seeking foreign regulatory approval could result in difficulties and costs and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets for our product candidates. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. There is a variety of risks associated with marketing our product candidates internationally, any of which could materially adversely affect our business. We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: • differing regulatory requirements and reimbursement regimes in foreign countries; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the FCPA, **Corruption of Foreign Public Officials Act (“CFPOA”)** or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations. Research and development of drugs targeting brain health disorders is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others. Discovery and development of new drugs targeting brain health disorders are particularly difficult and time-consuming, evidenced by the higher failure rate for new drugs for brain health disorders compared with most other areas of drug discovery. Any such setbacks in our clinical development could have a material adverse effect on our business and operating results. In addition, our later stage clinical trials may present challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in trials given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects. Due to the complexity of the human brain and the central nervous system, it can be difficult to predict and understand why a drug, including MM120, MM402 or any other product candidates, may have a positive effect on some patients but not others and why some individuals may react to the drug differently from others. Moreover, most of the patients we treat in clinical trials with MM120 and MM110 (prior to when we paused development of MM110) have previously been treated with other drugs or therapies. All of these factors may make it difficult **for us and any regulatory authority** to assess the prior use or the overall efficacy of our product candidates, including MM120 and MM402, **and may result in the termination of a development program, or delay or limit our ability to obtain regulatory approval**. We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected. Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including: • the size of the patient population required for analysis of the trial’s primary endpoints and the process for identifying patients; • identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications; • the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial; • safety profile, to date, of the product candidate under study; • the willingness or availability of patients to participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance, **which may be influenced by negative publicity**; • the willingness or availability of patients to participate in our trials, including due to impacts of public health emergencies **such as was seen during** the COVID- 19 pandemic; • perceived risks and benefits of our approach to treating patients for the indication the clinical trial is investigating; •

the proximity of patients to clinical sites; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • the availability of competing clinical trials; • the availability of new drugs approved for the indication the clinical trial is investigating; • clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and • our ability to obtain and maintain patient informed consents. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. In addition, any negative results we may report in clinical trials of MM120, MM402 or any other **product candidates or results from companies investigating similar** product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays in the enrollment for any clinical trial of MM120, MM402 or any other product candidates will likely increase our costs, slow down the approval process and delay or potentially jeopardize our ability to commence sales of our product candidates and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of MM120, MM402 or any other product candidates. We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our product candidates on our own or with suitable collaborators. While we are currently assembling a sales and marketing infrastructure, we have limited organizational experience in the sale or marketing of products. To achieve commercial success for any approved product candidates, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships. If our product candidates are approved for commercial sale, we plan on establishing our own market access and commercialization capabilities in primary markets in North America and in the EU. In select geographies, we might also consider relying on the support of a contract sales organization ("CSO"), or enter into commercialization arrangements with companies with relevant commercialization capabilities. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our product candidates effectively or to market our product candidates effectively since we have limited organizational experience in the sales and marketing of products. In addition, recruiting and training a sales force is expensive and time-consuming, and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates on our own include: • our inability to train an adequate number of HCPs to meet the demand for psychedelic treatment sessions (including with MM120 and any other product candidate within the therapeutic class); • the ability of HCPs to perform their roles consistently with our training and our guidelines for the administration of our product candidates; • our inability to recruit, train and retain effective market access and commercial personnel; • the inability of commercial personnel to obtain access to or educate adequate numbers of physicians on the benefits of prescribing MM120, MM402 or any other product candidates, if and when they are approved; • our inability to identify a sufficient number of treatment centers in third-party treatment sites to meet the demands of our product candidates; • the lack of complementary product candidates to be offered by our commercial personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • unforeseen costs and expenses associated with creating an independent market access and commercial organization; and • costs of market access and commercialization above those anticipated by us. If we enter into arrangements with third parties to perform market access and commercial services for any approved product candidates, the revenue or the profitability of these revenues to us could be lower than if we were to commercialize any product candidates that we develop ourselves. Such collaborative arrangements may place the commercialization of any approved product candidates outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our product candidates or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. We may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to commercialize our product candidates effectively, to set up sufficient number of treatment centers in third-party treatment sites, or to recruit, train and retain adequate number of HCPs to administer our product candidates. In addition, we are exploring ways in which we can use digital technology to improve the patient experience and product outcomes of our product candidates. Commercialization partners may lack incentives to promote our digital technology and we may face difficulties in implementing our digital technologies in third-party treatment sites through such third parties. If we do not establish commercial capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations. ~~Our digital technologies may not be successful, which may adversely affect our business, financial condition and results of operation. We may develop digital medicine projects in conjunction with our drug development programs that are intended to help facilitate the adoption and scalability of our product candidates, if they are approved and commercialized. In addition, we may work with technology companies or other third parties to acquire or develop new technologies to support our drug development programs. Our efforts to develop, acquire or integrate these technologies may 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 will depend on the degree of market access and acceptance of our product candidates, if approved, among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large. We may never have a product ~~candidate~~ **candidate** that is commercially successful. To date,

we have no product candidates authorized for marketing. Our product candidates require further clinical investigation, regulatory review, significant market access and marketing efforts and substantial investment before they can produce any revenue. Furthermore, if approved, our product candidates may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large, and we may not become profitable. The level of acceptance we ultimately achieve may be affected by negative public perceptions and ~~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 product candidates by healthcare professionals, patients, healthcare payors and health technology assessment bodies will depend on a number of factors, many of which are beyond our control, including, but not limited to, the following:

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

If our product candidates fail to gain **or maintain** market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some product candidates achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue. Our business and commercialization strategy depends on our ability to identify, qualify, prepare, certify and support third- party treatment sites offering any approved product candidate. If we are unable to do so, our commercialization prospects would be limited and our business, financial condition and results of operations would be harmed. If we are able to commercialize our product candidates, our success will be dependent upon our ability to identify, qualify, prepare, certify and support third- party treatment sites that can offer and administer our product candidates. Our commercial model of delivering our product candidates will also involve third- party HCPs before, during and after the administration session, which will be hosted in one of the third- party treatment sites. We intend to commercialize our product candidates by building close relationships with qualified third- party treatments sites where these HCPs will administer our product candidates. Because we intend to work only with third- party sites and providers who agree to adhere strictly to the administration protocols described in labeling or a REMS program, we may face limitations on the number of sites available to administer our product candidates. Any such limitations could make it impracticable or impossible for some potential patients to access our product candidates, if approved, which could limit the overall size of our potential patient population and harm the results of our future operations. Although we plan to train and certify such third- party treatment sites, conduct further research on and continuously improve our administration protocols, we expect this to involve significant costs, time and resources, and our efforts may not be successful. If we are unable to establish a sufficient network of third- party treatment sites certified under applicable standards, including regional, national, state or other applicable standards as needed to administer our product candidates, including the certifications that such third- party treatment sites may require, it would have a material adverse effect on our business and ability to grow and would adversely affect our results of operations and commercialization efforts. We expect the HCPs to be employed by the third- party treatment sites where the HCPs administer our product candidates. Third- party treatment sites could, for a number of reasons, demand higher payments for our product candidates or take other actions to increase their income from selling our product candidates, which could result in higher costs for payors and for our patients to get access to our product candidates. For example, legal regimes may require higher levels of licensure which force us to contract with third- party treatment sites that demand higher payment rates to administer our product candidates. In addition, third- party treatment sites may have difficulty meeting regulatory or accreditation requirements. Given the novel nature of our product candidates, third- party treatment sites may face additional financial and administrative burdens in order to deliver any approved product candidate, including adhering to a REMS program in the United States or a Risk Management Program (“ RMP ”) in the EU. The process for a third- party treatment site to become certified under a REMS program can be very costly and time- consuming, which could delay a third- party treatment site’ s ability to provide our product candidates and materially adversely affect our commercialization trajectory. Furthermore, third- party treatment sites will need to ensure that they have the necessary infrastructure and equipment in order to deliver our product candidates, such as adequate audio- visual equipment, ancillary equipment and sufficient administration rooms. This may deter third- party treatment sites from providing our product candidates and reduce our ability to expand our network and generate revenue. Our ability to develop and maintain satisfactory relationships with third- party treatment sites may otherwise be negatively impacted by other factors not associated with our operations and, in some instances, outside of our direct or indirect control, such as negative perceptions regarding the product use of lysergide, MDMA or other substances we use in our product

candidates, changes in Medicare and / or Medicaid or commercial payors reimbursement levels and other pressures on HCPs and consolidation activity among hospitals, physician groups and the providers. Reimbursement levels may be inadequate to cover third- party treatment sites' costs of delivering our product candidates. The failure to maintain or to secure new cost- effective contracts with third- party treatment sites may result in a loss of or inability to grow our network of third- party treatment sites, patient base, higher costs to our patients and us, HCP network disruptions and / or difficulty in meeting regulatory or accreditation requirements, any of which could have a material adverse effect on our business, financial condition and results of operations. We currently rely on qualified HCPs working at third- party clinical trial sites to administer our product candidates in our clinical trials and we expect this to continue upon approval, if any, of MM120, MM402 or any other product candidates. If third- party sites fail to recruit and retain a sufficient number of HCPs or effectively ~~manage~~ **oversee** their HCPs, our business, financial condition and results of operations would be materially harmed. We currently administer our product candidates in our clinical trials through qualified third- party HCPs working at third- party clinical trial sites. However, there are currently not enough trained HCPs to carry out our product candidates at a commercial scale, and our efforts to facilitate training and certification programs for HCPs may be unsuccessful. While we currently provide training to the HCPs and expect to continue providing trainings in the future (either directly or indirectly through third- party providers), we do not currently employ the HCPs who deliver our product candidates to patients and do not intend to do so in the future. Such HCPs are typically employed by third- party treatment sites. If our product candidates are approved for commercialization, third- party treatment sites may demand substantial financial resources from us to recruit and retain a team of qualified HCPs to administer our product candidates. If the third- party treatment sites fail to recruit, train and retain a sufficient number of HCPs, our ability to offer and administer our product candidates will be greatly harmed, which may in turn reduce the market acceptance rate of our product candidates. If this occurs, our commercialization prospects would be negatively affected and our business, financial condition and results of operations would be harmed. Although we currently provide training and expect to continue providing training to the HCPs (directly or through third- party providers), we generally rely on qualified and certified third- party treatment sites to manage the HCPs and monitor the administration of our product candidates and ensure that the administration process of our product candidates comply with dosing session guidelines. However, if not properly managed and supervised, there is a risk that HCPs may deviate from our dosing session guidelines, fail to follow the guidelines we have established, or abuse patients during administration sessions. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of product substances. Currently, we have no product candidates that have been approved for commercial sale; however, the use of our product candidates by us and our corporate collaborators in clinical trials, and the potential sale of any approved product candidates in the future, may expose us to liability claims. These claims might be made by patients who use our product candidates, HCPs, pharmaceutical companies, our corporate collaborators or other third parties that sell our product candidates. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If MM120, MM402 or any other product candidates causes adverse side effects during clinical trials or after regulatory approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with warnings that identify known potential adverse effects and describe which patients should not use MM120, MM402 or any other product candidates. Regardless of the merits or eventual outcome, liability claims may cause, among other things, the following: • decreased demand for our product candidates due to negative public perception; • injury to our reputation; • withdrawal of clinical trial participants or difficulties in recruiting new trial participants; • initiation of investigations by regulators; • costs to defend or settle the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue from product sales; and • the inability to commercialize our product candidates, if approved. It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business, financial condition and results of operations could be materially adversely affected. Liability claims resulting from any of the events described above could have a material adverse effect on our business, financial condition and results of operations. Risks Related to Regulatory Approval and other Legal Compliance Matters Lysergide, MDMA and other compounds used in our product candidates are listed as Schedule I controlled substances under the CSA in the U. S., and similar controlled substance legislation in other countries and any significant breaches in our compliance with these laws and regulations, or changes in the laws and regulations may result in interruptions to our development activity or business continuity. Lysergide, MDMA and other compounds used in our product candidates are categorized as Schedule I controlled substances under the CSA, and are similarly categorized by most states and foreign governments. Even assuming that MM120, MM402 or any other product candidates containing lysergide, MDMA and other Schedule I controlled substances are approved and ~~scheduled~~ **rescheduled** by regulatory authorities to allow their commercial marketing, the ingredients in such product candidates could continue to be Schedule I, or the state or foreign equivalent. Violations of any U. S. federal, state ~~or~~, local **or foreign** laws or ~~other foreign~~ regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, cessation of business activities, divestiture, or prison time. This could have a material

adverse effect on us, including on our reputation and ability to conduct **our** business, our financial position, operating results, profitability or liquidity or the market price of our publicly traded common shares. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or **defense or resolution** 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. Various federal, state, provincial and local laws govern our business in the jurisdictions in which we operate or currently plan to operate, and to which we export or currently plan to export our product candidates, including laws relating to health and safety, the conduct of our operations, and the production, storage, sale and distribution of our product candidates. Complying with these laws requires that we comply concurrently with complex federal, state, provincial and / or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure our compliance with these laws, we will need to invest significant financial and managerial resources. It is impossible for us to predict the cost of **compliance with** such laws or the effect they may have on our future operations. A failure to comply with these laws could negatively affect our business and harm our reputation. Changes to these laws could negatively affect our competitive position and the markets in which we operate, and there is no assurance that various levels of government in the jurisdictions in which we operate will not pass legislation or regulation that adversely impacts our business. In addition, even if we or third parties were to conduct activities in compliance with U. S. federal, state or local laws or other foreign laws in which we conduct activities, potential enforcement proceedings could involve significant restrictions being imposed upon us or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on our business, revenue, operating results and financial condition as well as on our reputation and prospects, even if such proceedings conclude successfully in our favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of our key executives, the seizure of corporate assets, and consequently, our inability to continue business operations. Strict compliance with U. S. federal, state and local laws or other foreign laws and with respect to Schedule I substances, such as lysergide and MDMA does not absolve us of potential liability under U. S. federal, state and local laws or other foreign laws, nor provide a defense to any proceeding which may be brought against us. Any such proceedings brought against us may adversely affect our operations and financial performance. **Disruptions at the FDA, including due to a reduction in the FDA's workforce and / or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies, which could negatively impact our business. The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel. Such changes and other disruptions at the FDA may increase the time to meet with the FDA and receive FDA feedback, review and / or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, the current President Trump administration (the " Trump Administration ") recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the Trump Administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. These budgetary pressures may reduce the FDA's ability to perform its responsibilities. In December 2024 and January 2025, we initiated our first and second Phase 3 clinical trials for our lead product candidate, MM120 ODT for the treatment of adults with GAD, and we plan to initiate our first Phase 3 clinical trial for MM120 ODT in MMD in the first half of 2025. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or marketing of MMD120 ODT, if approved, which could have a material adverse effect on our business.** Our business operations and our relationships with investigators, healthcare professionals, consultants, third- party payors and customers ~~may be currently or will~~ 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 ~~operations may be directly, or indirectly through our~~ relationships with investigators, healthcare professionals, customers and third- party payors, subject **us** to various U. S. federal and state healthcare laws and regulations, including, without limitation, the U. S. federal Anti- Kickback Statute (the " federal Anti- Kickback Statute "). HCPs, physicians and others play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. These laws impact, among other things, our research activities and proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third- party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved product candidates, and other parties through which we market, sell and distribute our product candidates for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U. S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). Finally, our current and future operations are subject to additional healthcare- related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. These laws include, but are not limited to, the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering,

receiving or paying any remuneration (~~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 or purchase, lease or order or the arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under U. S. federal and state healthcare programs such as Medicare and Medicaid. **A person or entity does not..... Act (the “ FCA ”)**. The definition of “ remuneration ” under the federal Anti- Kickback Statute has been interpreted to include anything of value. Further, courts have found that if “ one purpose ” of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated .A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (the “ FCA ”) . The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

- the federal civil and criminal false claims laws, such as the FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment **of government funds 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-penalties** for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’ s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the U. S. federal Health Insurance Portability and Accountability Act of 1996 (“ HIPAA ”), **health care fraud provisions**, which imposes criminal ~~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 **health care fraud provisions** without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“ HITECH ”), and their respective implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain HCPs, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information and their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the ~~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 ~~the EU~~ and other jurisdictions. The distribution of pharmaceutical products is subject to additional requirements and regulations, including licensing, extensive record- keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform ~~, 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 ~~, reputational harm,~~ and divert our management’ s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we process personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials (such as date of birth and initials), employee data, and sensitive third- party information. Our beta and development applications may include data from subject’ s mobile telephones and biometric wearables on subjects. Our information processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal information by us and on our behalf. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, HIPAA, as amended by the HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. To the extent that we act as a business associate to a HCP engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, such as restricting the use and disclosure of patient- identifiable health information, mandating the adoption of standards relating to the privacy and security of patient- identifiable health information, and requiring the reporting of certain security breaches to HCP customers with respect to such information. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Additionally, the California Consumer Privacy Act of 2018 ~~, as amended~~ **by the California Privacy Rights Act** (“ CCPA ”) imposes obligations on businesses to which it applies. These obligations include, but are not limited to, **data minimization obligations**, providing specific disclosures in privacy notices and affording California ~~residents~~ **consumers** certain rights related to their personal information. The CCPA allows for statutory fines for noncompliance (up to \$ 7, 500 per violation) and includes a private right of action for certain data breaches. ~~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 ~~, including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut~~ have enacted similar ~~comprehensive data-privacy laws~~ ~~or laws that broadly govern health~~ ~~example, Virginia passed the Consumer Data- data Protection Act,~~ **These laws impose new obligations or limitations in areas affecting our business** and Colorado passed ~~we continue to assess the impact of the these state legislation~~ **Colorado Privacy Act, on our business as additional information** both of which differ from the CPRA and ~~guidance become~~ **becomes effective in 2023 available. Many states have also used existing consumer protection statutes to regulate companies’ collection, use, and disclosure of personal information**. If we become subject to these or other data privacy laws at the state, local or federal level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and regulators). Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, in Canada, the Personal Information Protection and Electronic Documents Act (“ 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~~ **warnings** or **compliance orders** ~~definitive bans on information processing,~~ as well as fines

of up to 20 million Euros or 4 % of annual global revenue **for the preceding financial year**, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal information. The EU GDPR also provides that EU Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health information, which could result in differences between Member States, limit our ability to use and share personal information or could cause our costs to increase, and harm our business and financial condition. Certain jurisdictions have enacted data localization laws and cross- border personal information transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal information to countries outside of the EEA. The European Commission released a set of “ Standard Contractual Clauses ” that are designed to be a valid mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal information outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at- issue personal information. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal information out of the EEA. **In addition On July 10, 2023, the European Commission adopted its adequacy decision for the EU- U. S. Data Privacy Framework. Under this framework, personal data can flow freely from the EU to U. S. companies that participate in the Data Privacy Framework.** ~~laws~~ **Laws** in the UK ~~similarly also~~ restrict transfers of personal information outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal information protection. If we cannot implement a valid compliance mechanism for cross- border information transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe or elsewhere. The inability to import personal information to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal information processing capabilities and infrastructure in Europe and / or elsewhere at significant expense. We **are obligated** ~~may be subject to~~ **adhere to our** ~~contractual obligations and~~ **representations made in our** policies related to data privacy and security. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, **scrutiny and** enforcement actions by regulators or other adverse consequences. Additionally, we may also be bound by contractual obligations related to data privacy and security with our partners or CROs, and our efforts to comply with such obligations may not be successful. **Our obligations** **Laws, regulations, standards and** related to data privacy and security are quickly changing **in an increasingly stringent fashion**, creating some uncertainty as to the effective future legal framework **and our obligations**. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time- related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times ~~fail~~ **not meet all obligations** (or be perceived to have ~~failed~~ **not met our obligations**) ~~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 **scrutiny or** enforcement actions (e. g., investigations, fines, **civil and criminal** penalties **(including imprisonment of company officials)**, audits, inspections, and similar); litigation (including class- related claims); additional reporting requirements and / or oversight; ~~bans~~ **restrictions** on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those product candidates and decrease our ability to generate revenue. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford our product candidates, if approved. Our products must be scheduled as a Schedule II or lower controlled substance (i. e., Schedule III, IV or V) before they can be commercially marketed. Our ability to achieve acceptable levels of coverage and reimbursement for product candidates by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaboration partners to invest in the development of our product candidates. There is limited clinical data on the long- term efficacy of lysergide or MDMA on treating brain health disorders. Certain patients may need repeated treatments over their lifetime to avoid or re- treat a relapse of their disorder. This may increase treatment costs, making it more difficult for

us to secure reimbursement. Even if we obtain coverage for a given product candidate by third- party payors, the resulting reimbursement payment rates may not be adequate or may require patient out- of- pocket costs that patients may find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product candidate that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future –Third- party payors are increasingly challenging prices charged for product substances and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive product candidate is available. It is possible that a third- party payor may consider our current product candidates as substitutable and only offer to reimburse patients for the less expensive drugs. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed therapies at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on product candidates that we may develop. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor’ s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved therapies. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. Obtaining and maintaining reimbursement status is time- consuming and costly. No uniform policy for coverage and reimbursement for drug therapies exists among third- party payors in the United States. Therefore, coverage and reimbursement for drug therapies can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. We intend to seek approval to market MM120, MM402 and other product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly certain countries in Europe, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for our product candidates and may be affected by existing and future healthcare reform measures. **Third- party payors are increasingly challenging..... 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. In many countries, the prices of medical therapies are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical therapies but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU- wide, law and policy. The medicines regulatory regime in respect of the EU applies to the EEA, which comprises the EU Member States as well as Norway, Iceland and Liechtenstein. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of therapies in that context. In general, however, the healthcare budgetary constraints in many EU Member States have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with increasing EU and national regulatory burdens on those wishing to develop and market therapies, this could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to commercialize any product candidates for which we obtain marketing approval. EU pharmaceutical legislation may materially affect our ability to market and receive coverage for our product candidates in the EU Member States. On April 26, 2023, the European Commission adopted a proposal for a new Directive and a new Regulation to revise and replace the existing EU pharmaceutical legislation (the Regulation 726 / 2004 and the Directive 2001 / 83 / EC) and the legislation on medicines for children and for rare diseases (Regulation 1901 / 2006 and Regulation 141 / 2000 / EC, respectively). **The European Commission’ s proposal is currently being discussed by the European Parliament and the Council of Ministers the EU. On April 10, 2024, the European Parliament adopted its position on the proposals, the legislative processes of which are expected to continue in 2025 and beyond.** Much like the federal Anti- Kickback Statute prohibition in

the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal therapies is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and in respect of the UK (which is no longer a member of the EU), the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001 / 83 / EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU. Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and / or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in individual EU Member States and the particular requirements can therefore vary widely amongst the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In addition, in most foreign countries, including in many EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, individual EU Member States could restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. ~~A~~ **An EU** Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Moreover, the HTA Regulation of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. The outcome of an HTA Regulation will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA Regulation of the specific medicinal product currently varies between EU Member States. ~~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 **and UK** do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our product candidates is unavailable or limited in scope or amount, our revenue from sales and the potential profitability of our product candidates in those countries would be negatively affected. Moreover, increasing efforts by governmental and third-party payors in the EU, **the UK**, the United States and elsewhere to cap or reduce healthcare costs may cause such organizations to limit coverage and the level of reimbursement for newly approved therapies and, as a result, they may not cover or provide adequate payment for our product candidates. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific therapies. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new therapies. Enacted and future legislation may increase the difficulty of commercializing our product candidates and affect the prices we may charge for such product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. **Specifically Among other things**, there have been several recent U. S. Congressional inquiries, Presidential executive orders, and proposed **and enacted** federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, ~~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, 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 **units of certain** single-source drugs and biologics covered under Medicare, (2) imposes **certain** rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and (3) makes changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and replaces the existing coverage gap discount program with a new manufacturer discount program (beginning in 2025). These provisions began to take effect in fiscal year 2023 and are expected to have a significant impact on the pharmaceutical industry, and have been subject to legal challenges. ~~Further, the Biden administration released an additional executive order directing HHS to submit a report 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. **Additionally, some individual states have begun establishing Prescription Drug Affordability Boards to review high- cost drugs and, in some cases, set upper payment limits**. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. If we do not obtain protection under the Hatch- Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our investigational product candidates, our business may be materially harmed. In the United States, if all maintenance fees are paid on time, the natural expiration of a patent is generally 20 years from its earliest non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our investigational product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive therapies. Given the amount of time required for the development, testing and regulatory review of new investigational therapies, patents protecting such candidates and concomitant therapies might expire before or shortly after such candidates and concomitant therapies are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing therapies similar or identical to ours. Depending upon the timing, duration and conditions of FDA marketing approval of MM120, MM402 or any other product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the " Hatch- Waxman Act"), and similar legislation in the EU. The Hatch- Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term loss during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method of manufacturing it may be extended. However, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will not be lengthened and third parties, including our competitors, may obtain approval to market competing therapies sooner than we expect. As a result, our revenue from applicable product candidates could be materially reduced and our business, financial condition, results of operations, and prospects could be materially harmed. We could experience difficulty enforcing our contracts. Due to the nature of our business and the fact that our contracts involve certain substances whose usage is not legal under U. S. federal law and in certain other jurisdictions, we may face difficulties in enforcing our contracts in U. S. federal and state courts. The inability to enforce any of our contracts could have a material adverse effect on our business, prospects, financial condition and results of operations. In order to manage our contracts with contractors, we ensure that such contractors are appropriately licensed at the state and federal level in the United States and at the appropriate level in other jurisdictions. Were such contractors to operate outside the terms of these licenses, we may experience an adverse effect on our business, including the pace of development of our product candidates. Investors in certain jurisdictions may have difficulty in enforcing judgments and effecting the service of process on us. The enforcement by investors of civil liabilities under the United States federal or state securities laws may be affected adversely by the fact that we are incorporated under the laws of the Province of British Columbia. It may not be possible for investors to enforce judgments obtained in the United States courts against us based upon the civil liability provisions of United States federal securities laws or the securities laws of any state of the United States. There is some doubt as to whether a judgment of a United States court based solely upon the civil liability provisions of United States federal or state securities laws would be enforceable in Canada against us. There is also doubt as to whether an original action could be brought in Canada against us to enforce liabilities based solely upon United States federal or state securities laws. In addition, all of our directors and officers reside outside of Canada. Some or all of the assets of such persons may be located outside of Canada. Therefore, it may not be possible for investors to collect or to enforce judgments obtained in Canadian courts predicated upon the civil liability provisions of applicable Canadian securities laws against such persons. Moreover, it may not be possible for investors to effect service of process within Canada upon such persons. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our clinical development programs and the significant number of brain health disorders our products are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to ~~monitor~~ **identify the comment** and comply with applicable adverse event reporting obligations. **Additionally**, ~~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 **FDA restrictions on advertising and promoting unapproved new drugs or other foreign governmental** restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any

social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business. The production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions. Our product candidates contain controlled substances, including psychedelic substances, which are subject to strict legal requirements in certain jurisdictions where we will produce and sell our products. Certain jurisdictions may not allow the use or production of the substances included in our products, nor provide any possibilities for an exemption or regulatory approval that could allow for the lawful use or production of such substances. In addition, these jurisdictions may prohibit any form of contributing to the production or use of these drugs and may also directly or indirectly prohibit the receipt of any benefits following from the production and sale of these substances. Under circumstances, this may have consequences for the legality of the purchase of our shares or receipt of dividends in or from foreign jurisdictions. If certain foreign authorities consider it illegal to invest in our company, this will negatively affect the possibility of commercializing and generating revenue in the country of interest. Any investigations of authorities against foreign investors could generate negative publicity. We cannot predict the likelihood of foreign authorities taking such a point of view or taking any actions against investors in certain jurisdictions. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our business activities may be subject to the U. S. Foreign Corrupt Practices Act ("FCPA"), Corruption of Foreign Public Officials Act (Canada) ("CFPOA") and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U. S., Canadian and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our business activities may be subject to the FCPA, CFPOA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA and CFPOA generally prohibit companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a government official in order to influence official action or otherwise obtain or retain business. The FCPA and CFPOA also require public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U. S. and non-Canadian governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition. In addition, our products may be subject to U. S., Canadian and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. and Canadian export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U. S. and Canadian sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our product candidates or limitation on our ability to export or sell our product candidates would likely adversely affect our business. Risks Related to Employee Matters, Managing our Growth and Other Risks Related to our Business Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees. To succeed, we must recruit, retain, manage

and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed. Additionally, we rely on scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. If we are unable to maintain consulting relationships with our scientific **founders and clinical advisors** or if they provide services to our competitors, our development and commercialization efforts will be impaired, and our business will be significantly harmed. We face competition from other biotechnology and pharmaceutical companies and our financial condition and operations will suffer if we fail to effectively compete. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors include large, well- established pharmaceutical companies, biotechnology companies, academic and research institutions developing products for the same indications we are targeting and competitors with existing marketed therapies. Many other companies are developing or commercializing therapies to treat the same diseases or indications for which our product candidates may be useful. Many of our competitors have substantially greater financial, technical and human resources than we do, and have significantly greater experience than us in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly than we do. Our ability to compete successfully will largely depend on: (1) the efficacy and safety profile of our product candidates relative to marketed products and other product candidates in development; (2) our ability to develop and maintain a competitive position in the product categories and technologies on which it focuses; (3) the time it takes for our product candidates to complete clinical development and receive marketing approval; (4) our ability to obtain required regulatory approvals; (5) our ability to commercialize any of our product candidates that receive regulatory approval; (6) our ability to establish, maintain and protect intellectual property rights related to our product candidates; and (7) acceptance of any of our product candidates that receive regulatory approval by physicians and other HCPs and payers. Competitors have developed and may develop technologies **and compounds** that could be the basis for products that challenge ~~the discovery research capabilities of~~ **MM120 ODT**, **MM402** or other product candidates we are developing. Some of those products may have an entirely different approach or means of accomplishing the desired product effect than our product candidates and may be more effective or less costly than our product candidates. The success of our competitors and their product candidates relative to our **product candidates technological capabilities and competitiveness** could have a material adverse effect on the ~~future preclinical studies and clinical trials of~~ **development programs for MM120 ODT, MM402 or other product candidates, including as they may impact** our ability to **raise additional capital, on favorable terms or at all, and our 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 MM120, MM402 or other product candidates.~~ 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, 2023-2024, we had 57-74 full-time and part-time employees. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our internal development efforts effectively, including the FDA and other comparable foreign regulatory agencies' review process for MM120 ODT, MM402 or any other product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully develop and, if approved, commercialize MM120 ODT, MM402 or other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of MM120 ODT, MM402 or any other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and / or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize MM120 ODT, MM402 or other product candidates and, accordingly, may not achieve our research, development and commercialization goals. If our information technology systems or data, or those of third parties upon which we rely, are ~~of or~~ were compromised, we could experience adverse consequences resulting from such compromise, including regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive information, including personal information (such as health-related information), data related to clinical trials, intellectual property, and trade secrets. We may rely upon third parties - party service providers and technologies to operate critical business systems to process ~~such 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 third parties authorized to access or our systems 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 ~~or authorized third-party~~ misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of information or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a ~~breach of~~ **breach of cybersecurity incident** or disruption to our information technology systems or the third-party information technology systems that support us and our services. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. For example, we have employees and consultants upon which we rely to support our business located in geographical proximity to unstable regions and regions experiencing (or expected to experience) geopolitical or other conflicts, such as consultants in Slovakia, a country that borders Ukraine which was attacked by Russia in February 2022 through various means, including

cyberattacks. Any of the previously identified or similar threats could cause a **security-cybersecurity breach-incident** or other interruption. A **security-cybersecurity breach-incident** or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to information. A **security-cybersecurity breach-incident** or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against **security-cybersecurity breaches-incidents**. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standard or reasonable security measures to protect our information technology systems and data. Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of third parties upon which we rely (including sites performing our clinical trials), there can be no assurance that these measures will be effective **or that a court or regulatory authority will consider them to be appropriate or reasonable**. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a **security-cybersecurity breach-incident** has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified **potential** vulnerabilities. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Applicable data privacy and security obligations may require us to notify relevant stakeholders of **security-cybersecurity breaches-incidents**. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a **security-cybersecurity breach-incident** or are perceived to have experienced a **security-cybersecurity breach-incident**, we may experience adverse consequences. These consequences may include: government **scrutiny or** enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of information); financial loss; **delays in reporting our financial results;** and other similar harms. **Security breaches-Cybersecurity incidents** and attendant consequences may cause customers to stop using our services, deter new clinical trial participants from participating in our services, and negatively impact our ability to grow and operate our business. **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 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 or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or 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 is a substantial amount of litigation, both within and outside other-- the proceedings-United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, reexamination, derivation and administrative law proceedings, inter partes review and post- grant review before the USPTO, as well as oppositions and similar processes in reexamination proceedings before the U. S. Patent and Trademark Office ("USPTO"), and Canadian Intellectual Property Office ("CIPO"), and corresponding foreign jurisdictions 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 or other business activities 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, in addition, we, third parties may face, obtain patent rights in the future and claims claim from non-practicing that use of our technologies infringes upon these rights. If any third-party entities that have no relevant patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product revenue and against whom candidates, any molecules formed during the manufacturing process our- or own any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent portfolio were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may have no deterrent effect be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires.** In 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 **case** us to incur substantial expenses and, **such** 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 **license** 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 **commercially reasonable** 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 **infringement or other intellectual property** 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, pay royalties or redesign our affected products,** which may be impossible or require substantial time and monetary expenditure. **We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.** In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and / or Supplementary Protection Certificates in the **EU 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. **Furthermore, as the patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event,**

we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties. We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that ~~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~~ **Failure** to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products. We may become involved in lawsuits to protect or enforce ~~our any future~~ **patents, the patents of our licensors or our other intellectual property rights**, which could be expensive, time- consuming and unsuccessful. ~~We have issued~~ **Competitors may infringe or otherwise violate our** patents, ~~the~~ and when and if we do obtain additional issued patents **of our licensors or our other intellectual property rights**, we may discover that competitors are infringing these patents. **To counter infringement or unauthorized use, we may be required to file legal claims, which can be Expensive-expensive and time- consuming . In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation may be required to enforce- or defense proceedings could put one or more of our patents at risk . If we or one of our- or** ~~collaboration partners were to- interpreted narrowly and could put our patent applications at risk of not issuing. The initiate-initiation~~ **legal proceedings of a claim** against a third party **may also cause to enforce a patent covering one of our product candidates, the defendant could counterclaim third party to bring counter claims against us such as claims asserting that the our patent patents are 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 , written description, or lack of patentable subject matter . Grounds for an unenforceability assertion could include be an allegation that someone involved in connected with the prosecution of the patent withheld relevant or- material information related to the patentability of the invention from the USPTO or CIPPO- or made a materially misleading statement during prosecution . Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as ex parte reexaminations, inter partes review or post- grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation .** The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. **We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees** Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could

ultimately be forced to cease use of such trademarks. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during **any this type of** 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~~ **an adverse effect** on the market price of ~~our securities~~ **common shares**. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We employ individuals and retain independent contractors and consultants ~~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~~ **seek to ensure protect our ownership of intellectual property rights by ensuring** that our **agreements with our** employees, consultants and independent contractors, **consultants, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights** not use the proprietary information or know-how of others in inventions to their work for us and, we ~~may be~~ **are not currently** subject to ~~any~~ **claims that they we or our employees, consultants or independent contractors have done so, we may in inadvertently or otherwise used or disclosed confidential information of such persons' former companies or the other future third parties. We may also** be subject to ~~claims that~~ **such claims persons or other third parties have an ownership interest in our intellectual property**. Litigation may be necessary to defend against these claims. ~~If~~ **There is no guarantee of success in defending these claims, and if** we fail to ~~in defend~~ **defending** any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact ~~such as exclusive ownership of, our~~ **or business right to use, valuable intellectual property**. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. In addition, while we ~~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~~ **protection** for our **technology and** product candidates, **or if the scope of the patent protection obtained is not sufficiently broad**, we may not be able to ~~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~~ **compete effectively** advantage our patents may have otherwise afforded us. While our principal focus in ~~our markets~~ **We** 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, **trademarks**, and confidentiality agreements to protect ~~the~~ **our own** intellectual property related to our product candidates and development programs. Our ~~success~~ **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~~ **The patent prosecution** process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. **If the patent applications we hold or have in- licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business. The patents and patent applications that we own or in- license may fail to result in issued patents with claims that protect our present and future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our present or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any present or future product candidates or methods of using such. Further, if we encounter delays**

in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. The patent positions—position of biopharmaceutical companies are generally are highly uncertain and involve complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for which legal principles remain unresolved patent protection of such inventions. As a result, of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. The pending patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States, Canada or in other foreign countries for many reasons. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U. S. Patent and Trademark Office (“USPTO”) or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, patents do not 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. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. The issuance of a In addition, recent changes to the patent laws of is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such provide additional procedures for third parties to challenge challenges the validity may result in loss of exclusivity 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 or freedom to operate product candidates is challenged, then it could threaten our or 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 being narrowed, invalidated our or held unenforceable applications and patents. If third parties have filed such applications after March 15, 2013, a derivation proceeding in whole the United States can be initiated by such third parties to determine whether our or invention was derived from theirs. In addition to our issued patents, we have patent applications in part 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 limit our deprive us of the ability to prevent stop others from using the or commercializing similar or identical technologies technology claimed in such and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. Further In certain instances, if we encounter patent term can be adjusted to recapture a portion of delays delay by the USPTO in examining the patent application (patent term

adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review approvals, the period (patent term extension), or both. The scope of time during which we could market a product candidate under patent protection could ~~may also~~ be reduced ~~limited~~. ~~Without~~ We have filed patent ~~protection~~ applications directed to our own proprietary formulations and processes for our ~~current or future~~ product candidates when ~~we have believed securing~~ ~~may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates,~~ patents ~~protecting such candidates might~~ ~~may afford a competitive advantage. For example, the patents covering lysergide and MDMA have expired~~ ~~expire before~~. We have developed our ~~or shortly after such candidates~~ own proprietary formulations or manufacturing methods for these products that we believe are ~~commercialized. As a result, our owned and licensed patent portfolio may~~ 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 MM120, MM402 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 MM120. In contrast to our patent applications directed to formulations of MM120, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with ~~sufficient rights~~ competitive advantage, were not developed by us to ~~exclude others from commercializing products similar or identical to~~ avoid third-party patents. As in the case of our ~~ours~~ 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. ~~Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent.~~ The USPTO, CIPO and various foreign ~~governmental national or international~~ patent agencies require compliance with a number of procedural, documentary, fee payment and other ~~similar~~ provisions during the patent ~~application~~ process. ~~In~~ ~~While, in~~ many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. ~~However~~, there are situations in which noncompliance can result in abandonment or lapse of ~~a the~~ patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. ~~Noncompliance~~ ~~In such an event~~ ~~events that could result in abandonment or lapse of patent rights include~~, but are not limited to, failure to timely file national and regional stage patent applications based on our ~~international patent application, failure to respond to official actions within prescribed time limits, non-~~ payment of fees and failure to properly legalize and submit formal documents. ~~If we or our licensors fail to maintain the patents and patent applications covering or present and future product candidates, our~~ competitors might be able to enter the market ~~earlier than~~, ~~which~~ would otherwise have been the case ~~an adverse effect on our business~~. We may not be able to protect our intellectual property rights throughout the world, ~~which could impair our business~~. Filing, prosecuting, defending and enforcing patents ~~and trademarks~~ on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States ~~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 ~~or trademark~~ applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States ~~and Canada~~ or importing products made using our inventions into the United States, ~~Canada~~ or other jurisdictions ~~and we may not be able to use our trademarks in all countries or prevent others from using or registering similar trademarks~~. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States ~~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 ~~or the patent law of other countries or jurisdictions~~ could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. ~~The~~ 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 ~~implemented~~ wide-ranging patent reform legislation.

The U. S. Supreme Court has ruled, including the Leahy-Smith America Invents Act (the "America Invents Act"), signed into law on **several** 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 **cases** 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 **years** court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, **either narrowing** 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 or** **weakening** the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on **future** actions by the **United States U. S.** Congress, the **Federal federal Courts 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 **have licensed or that we** might obtain in the future. **If we are unable to maintain effective proprietary rights** **For example, recent decisions raise questions regarding the award of patent term adjustment (PTA)** **for our product candidates patents in families where related patents have issued without PTA. Thus**, we **may it cannot be said with certainty how PTA will / will not be viewed** **able to compete effectively in future and whether** **patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries our- or** **markets- jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of** **European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed**. While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know- how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy. Although we **expect require** all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate

remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “ first- to- file ” laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions. We may be subject to claims challenging the inventorship of our patent filings and other intellectual property. We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co- inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are a party to research and license collaborations, including an exclusive worldwide license agreements with University Hospital Basel, pertaining to lycerigide and other research products. We are also party to a license agreement with Catalent, pursuant to which we were granted an exclusive license to use their Zydis technology in the development of MM120. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. In the event we breach any of our obligations under these agreements, we may incur significant liability to our research and licensing partners. Disputes may arise regarding intellectual property subject to a research licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patents and other rights; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and our collaborators; • the priority of invention of patented technology. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business. In addition, our license agreement with Catalent imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. Any unsecured, **If we breach any material obligations, breach under these license agreements could result in our or use loss of rights to practice the patent rights and other-- the intellectual property licensed to us under in an unauthorized manner, we may be required to pay damages and these-- the agreements licensor (s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology**, and could compromise our development and commercialization efforts for our product candidates. **Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish our company’ s name and logo, as well as to distinguish the name and logos used with any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. successful in obtaining or For example 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, our U. S. trademark registration for MINDMED covers a narrower list of goods than we initially sought to including include in the registration University Hospital Basel and MindShift Compounds AG. Because 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-- the USPTO cited a proprietary rights. We may be unable to acquire or in- license compositions, methods of use, processes or other third- party intellectual property trademark application as an obstacle to registration with a broader list of goods and services. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. Under U. S. law, registration of a trademark requires lawful use of the mark in commerce. The USPTO may determine that our use of the trademark for our goods and services does not meet the statutory requirements for lawful use in commerce for registering a trademark if, for example, our products remain on Schedule I of the CSA. Consequently, the USPTO may refuse to register our trademarks, and existing registrations could be subject to cancellation. Furthermore, our ability to enforce our trademarks in U. S. federal courts or to prevent others from using similar marks may be limited due to these federal restrictions. This could lead to increased risks of infringement, dilution of our brand, and legal disputes that are difficult to resolve favorably. We may face analogous restrictions on protecting and enforcing trademarks in other jurisdictions internationally, and the requirements for lawful use of trademarks vary from country to country. The cost to us of any trademark litigation or other trademark proceeding**

such as an opposition or cancellation action, even if resolved in our favor, could be substantial. Trademark litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of trademark litigation or other proceedings could impair our ability to compete in the marketplace. In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights from of 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 **acceptable** 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 **FDA** 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 **MM120 ODT**, **MM402 R(-)-MDMA** and **our** other controlled substances incorporated in our product candidates, and we will rely on third parties to manufacture these substances for commercial supply, if approved. If any third-party provider fails to meet its obligations manufacturing our product candidates, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substances and the commercialization of any product candidates, if approved, could be stopped, delayed or made commercially unviable, less profitable or may result in enforcement actions against us. We do not currently have, nor do we plan to acquire, the infrastructure or capability necessary to manufacture MM120, MM402 or any other product candidates, including the lysergide, R(-)-MDMA or other controlled substances incorporated into such product candidates. We rely on, and expect to continue to rely on, CDMOs, for the development, manufacture and production of the lysergide used in our product candidates administered in our clinical trials and will continue to rely on such CDMOs for the development, manufacture, **testing** and production of any commercial supply, if our product candidates are approved. Currently, we engage with multiple CDMOs for all activities relating to the development, manufacture and production of all **components incorporated in our product candidates including API, bulk drug product, and final drug product**. Reliance on third-party providers, such as CDMOs, exposes us to more risk than if we were to manufacture our product candidates **at**. We do not control the manufacturing processes of the CDMOs we contract with and are dependent on those third parties for the production of MM120, MM402 or **our own facilities**. While **we subject** any other product candidates in accordance with relevant regulations (such as the FDA's GLP, cGMPs or **our** similar regulatory requirements outside the U.S.) 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 MM120, MM402 or any of our other product candidates, including our current supplier of active pharmaceutical ingredient, **have not to strict manufacturing requirements and rigorous testing requirements in order to ensure compliance with cGMP and the other past been manufacturing regulations, such suppliers are still** subject to inspection by the FDA and **other applicable regulatory** / 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 MM120, MM402 or any other product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of MM120, MM402 or any other product candidates and harm our business and results of operations. If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for MM120 **ODT**, MM402 or any other product candidates, we could experience delays in our research or planned clinical studies or commercialization. In addition, quality issues may arise during scale-up activities. We could be unable to find alternative suppliers of acceptable **capability and** quality, in the appropriate volumes and at an acceptable cost. For example, we have engaged a single supplier for the production of lysergide. Because lysergide is a controlled substance and subject to increased regulation resulting from that classification, if we are unable to **reply-rely** on our current supplier for lysergide, we may experience delays or increased costs in obtaining an alternative provider or we may be unable to find an alternative supplier on acceptable terms. Our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, may significantly delay our preclinical studies and clinical trials and the commercialization of our product candidates, if approved, which would materially adversely affect our business, prospects, financial condition and results of operations. In complying with the manufacturing requirements of the FDA, the DEA and other comparable foreign authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the product candidates meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of product candidates and shutting down of production, any of which could materially adversely affect our business, prospects, financial condition and results of operations. We and any of these third-party suppliers may also be subject to audits by the FDA, the DEA and other comparable foreign authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our

ability to develop and commercialize the product candidates could suffer significant interruptions. We face risks inherent in relying on a limited number of CDMOs, as any disruption, such as a fire, natural hazards or vandalism at the CDMO, or a change in operations as a result of the sale of one of our CDMOs, could significantly interrupt our manufacturing capability. For example, we have engaged Catalent ~~as for certain contract manufacturing and other~~ **the exclusive supplier of services related to our planned MM120 ODT Phase 3 clinical trials**. On February 5, 2024, Catalent ~~the that would be merging with~~ **Novo Holdings A / S (“ Novo Holdings ”). On December 18, 2024,** Catalent **announced the closing of its merger with Novo Holdings**. While we ~~do have not experienced~~ **currently anticipate** any impact on our relationship with Catalent **to date**, the proposed merger may impact Catalent’s management and operations, which could significantly **interrupt** our **manufacturing capability supply chain** and require us to find a new CDMO to provide clinical **and commercial** supplies, if MM120 **ODT** is approved. We currently do not have disaster recovery facilities available **for our product candidates**. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial **time and** capital on our part, which we may not be able to obtain on commercially acceptable terms or at all, and we would likely experience months of manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we **will may** be unable to satisfy manufacturing needs on a timely basis or at all. In addition, operating any new facilities may be more expensive than operating our current facility, and business interruption insurance may not adequately compensate us for any losses that may occur, in which case we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have a material adverse effect on our business, including placing our financial stability at risk. We rely, and expect to continue to rely, on third parties, including independent clinical investigators, academic collaborators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic collaborators and third- party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third- party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the national competent authorities of the EU Member States, the MHRA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators, academic collaborators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure, or the failure of our third- party contractors and CROs, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. Further, these investigators, academic collaborators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators, academic collaborators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates that we develop. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. In addition, investigators, academic collaborators and CROs may have difficulty staffing, undergo changes in priorities or become financially distressed or form relationships with other entities, some of which may be our competitors, any of which materially adversely affect our business. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. There is a limited number of third- party service providers that specialize in or have the expertise required to achieve our business objectives. If any of our relationships with these third- party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs, academic collaborators or investigators on commercially reasonable terms or at all. If CROs, academic collaborators or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding additional CROs (or investigators) involves additional cost and requires management time and focus. In addition, delays occur during the natural transition period when a new CRO commences work, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business or financial condition and prospects. If we decide to establish collaborations, but are not able to establish those collaborations on commercially reasonable

terms, we may have to alter our development and commercialization plans. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to, and the manner in which they perform their obligations under, these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may rely on third parties to conduct development, manufacturing, and / or commercialization activities, and except for remedies available to us under our collaboration agreements, we have limited ability to control the conduct of such activities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to the Securities Markets and Ownership of our Common Shares The price of our common shares is volatile. The trading price of our common shares is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume

fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common shares, regardless of our actual operating performance. In addition to the factors discussed in this “ Risk factors ” section and elsewhere in this **periodic Annual report 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 ~~2-1, 2023-2024~~ to December ~~29-31, 2023-2024~~, the closing price of our common shares on the Nasdaq Capital Market ranged from as low as \$ ~~2-3, 43-55~~ to as high as \$ ~~4-11, 75-93~~ and on the Cboe Canada exchange (formerly "NEO Exchange") ranged from as low as CAD \$ ~~3.36~~ to as high as CAD \$ ~~6.51~~ and daily trading volume ranged from approximately ~~95-202, 500-226~~ to ~~5-38, 178-105, 100-520~~ shares on the Nasdaq Capital Market and daily trading volume ranged from approximately ~~1,050~~ to ~~176,512~~ shares on the Cboe Canada exchange (formerly "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. Our operating results may fluctuate significantly, which would make our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which would make it difficult to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock- based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee’s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying share price and share price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

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

pronouncements or changes in our accounting policies; and • the changing and volatile global economic and political environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common shares could decline substantially. Such a share price decline could occur even when we have met any previously publicly stated guidance we may provide. We are an “ emerging growth company, ” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common shares less attractive to investors. We are an “ emerging growth company, ” as defined in the Jumpstart Our Business Startups Act of 2012 (the “ JOBS Act ”). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including: • being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “ Management ’ s Discussion and Analysis of Financial Condition and Results of Operations ” disclosure in this Annual Report; • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended (Sarbanes- Oxley Act); • not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor ’ s report providing additional information about the audit and the financial statements; • reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements; and • exemptions from the requirements of holding nonbinding advisory shareholder votes on executive compensation and shareholder approval of any golden parachute payments not previously approved. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year (1) in which we have more than \$ 1. 235 billion in annual revenue; (2) on which we qualify as a “ large accelerated filer, ” with at least \$ 700. 0 million of equity securities held by non- affiliates; (3) on which we have issued more than \$ 1. 0 billion in non- convertible debt securities during the prior three- year period; and (4) following the fifth anniversary of the date of the first sale of common equity securities of the issuer under an effective Securities Act registration statement. Notwithstanding the above, we are also currently a “ smaller reporting company, ” meaning that we had a public float of less than \$ 250-700. 0 million **as of the last business day of our most recent second fiscal quarter** and annual revenues of less than \$ 100. 0 million during the most recently completed fiscal year. If we are still considered a “ smaller reporting company ” at such time as we cease to be an “ emerging growth company, ” we will be subject to increased disclosure requirements. However, the disclosure requirements will still be less than they would be if we were not considered either an “ emerging growth company ” or “ smaller reporting company. ” Specifically, similar to “ emerging growth companies, ” “ smaller reporting companies ” are able to provide simplified executive compensation disclosures in their filings; ~~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. 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 our any applicable free writing prospectus filed with the SEC filings** in determining whether to purchase our securities. Information provided by third parties may not be reliable or accurate and could materially impact the trading price of our common shares, which could cause losses to your investments. Our business and operations could be negatively affected if we become subject to any securities litigation or shareholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price. In the past, following periods of volatility in the market price of a company ’ s securities, securities class action litigation has often been brought against that company. Shareholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock

price of our common shares or other securities or other reasons may in the future cause us to become the target of securities litigation or shareholder activism. For example, a group of our shareholders nominated four director candidates for election to our six- member Board at our 2023 annual general meeting of shareholders, and waged a proxy contest in support of their candidates and in opposition to four of our Board' s director nominees. Securities litigation and shareholder activism, including potential proxy contests, could result in substantial costs and divert management' s and our Board' s attention and resources from our business. Further, a future proxy contest, unsolicited takeover proposal, or other shareholder activism relating to the election of directors or other matters would most likely result in significant legal fees and proxy solicitation expenses and require significant time and attention. Even if not formally launched, the potential of a proxy contest, unsolicited takeover proposal, or other shareholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and shareholder activism. Actions of activist shareholders against us have been and could be disruptive and costly, may cause uncertainty about the strategic direction of our business, result in litigation, divert management' s and our Board' s attention and resources, and may have an adverse effect on our business and stock price. From time to time, we may be subject to proposals by activist shareholders urging us to take certain corporate actions or to nominate certain individuals to our board of directors. For example, a group of our shareholders nominated four director candidates for election to our six- member Board at our 2023 annual general meeting of shareholders, and waged a proxy contest in support of their candidates and in opposition to four of our Board' s director nominees. Future activist shareholder matters, including a proxy contest and potential related litigation, could have a material adverse effect on us for the following reasons:

- Such shareholders may attempt to effect changes in our governance and strategic direction or to acquire control over our Board or the Company.
- While we welcome the opinions of all shareholders, responding to proxy contests and related litigation by shareholders has been, and could be, costly and time- consuming, and could disrupt our operations, and divert the attention of our board of directors, management team and other employees away from their regular duties and the pursuit of business opportunities to enhance shareholder value.
- Perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business, instability or lack of continuity, which may cause concern to our existing or potential collaboration partners, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners any of which could adversely affect our business and operating results.
- Perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist shareholder initiatives may harm our ability to attract new investors, and could cause our stock price to experience periods of volatility or stagnation based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Our articles and certain Canadian legislation contain provisions that may have the effect of delaying or preventing certain change in control transactions or shareholder proposals. Any of these provisions may discourage a potential acquirer from proposing or completing a transaction that may have otherwise presented a premium to our shareholders. Certain provisions of our articles and certain Canadian legislation, together or separately, could discourage or delay certain change in control transactions or shareholder proposals. Under our articles, we are required to comply with certain advance notice procedures for nomination of candidates for election as directors at shareholders' meetings. These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management. The Investment Canada Act requires that a non- Canadian must file an application for review with the Minister responsible for the Investment Canada Act and obtain approval of the Minister prior to acquiring control of a " Canadian business " within the meaning of the Investment Canada Act, where prescribed financial thresholds are exceeded. Furthermore, limitations on the ability to acquire and hold our Common Shares may be imposed by the Competition Act (Canada). This legislation permits the Commissioner of Competition (the " Commissioner"), to review any acquisition or establishment, directly or indirectly, including through the acquisition of shares, of control over or of a significant interest in our company. Otherwise, there are no limitations either under the laws of Canada or the Province of British Columbia, or in our articles on the rights of non- Canadians to hold or vote our common shares. We are governed by the corporate laws in British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws in Delaware, United States. There are material differences between the BCBCA and the Delaware General Corporation Law (the " DGCL "), including the following: (i) under the BCBCA, significant corporate actions, such as continuances, certain amalgamations, sales, leases or other dispositions of all or substantially all of the undertaking of a company (other than in the ordinary course of business), liquidations, dissolutions and certain arrangements, require the approval of at least two thirds of the votes cast by a company' s shareholders, whereas under Delaware law, a majority of the total voting power of outstanding shares entitled to vote on the matter is generally required for sch matters; (ii) under the BCBCA shareholders holding at least 1 / 20 of our issued and outstanding common shares can requisition a general meeting at which any matters that can be voted on at our annual meeting can be considered, whereas the DGCL does not give this right; (iii) our articles require two- thirds majority vote by shareholders to pass a resolution for one or more directors to be removed, whereas DGCL only requires the affirmative vote of a majority of the shareholders; however, many public company charters limit removal of directors to a removal for cause; and (iv) our articles may be amended by resolution of our directors to alter our authorized share structure, including to (a) consolidate or subdivide any of our shares and (b) alter the identifying name of any of our shares, whereas under DGCL, a majority vote by shareholders is generally required to amend a corporation' s certificate of incorporation and a separate class vote may be required to authorize alterations to a corporation' s authorized share structure. We cannot predict if investors will find our common shares less attractive because of these material differences. If

some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile. If we fail to meet all applicable listing requirements and either Nasdaq or Cboe Canada determines to delist our common shares, or if we elect to voluntarily delist from Cboe Canada, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease. Our common shares are currently listed on both Nasdaq and Cboe Canada exchanges. There can be no assurance that we will maintain compliance with the requirements for listing our common shares on Nasdaq or Cboe Canada. If we fail to meet all applicable listing requirements for either the Nasdaq or Cboe Canada, our common shares could be delisted from such the exchanges exchange. In addition, we may voluntarily elect to delist from Cboe Canada as a result of the costs to comply with the applicable listing requirements. Delisting could adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common shares. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. **Effective April 10, 2024, we voluntarily delisted our common shares from Cboe Canada due to our belief that the trading volume of our common shares on Cboe Canada no longer justified the expense and administrative requirements associated with maintaining the dual listing.** General Risk Factors 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. 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, 2023-2024, we had available U. S. federal NOL carryforwards of \$ 128.165.35 million which can be carried forward indefinitely. We also have available state NOL carryforwards of approximately \$ 17.20.0 million as of December 31, 2023-2024, of which will begin to \$ 0.2 million can be carried forward indefinitely and \$ 16.8 million expire in 2037 beginning December 31, 2028 and are subject to limitation on use. In addition, under Sections 382 and 383 of the U. S. Internal Revenue Code of 1986 (as amended) (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5- percent shareholders" that exceeds 50 percentage points over a rolling three- year period), the corporation's ability to use its pre- ownership change NOLs and certain other pre- ownership change tax attributes to offset its post- ownership change taxable income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our share ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership of the Company. As a result, our ability to utilize our NOLs and certain other tax attributes could be limited. There is also a risk that regulatory changes, such as suspensions on the use of NOLs or other unforeseen changes, could cause our existing NOLs to expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. Consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. We will be subject to Canadian and United States tax on our worldwide income. We will be deemed to be a resident of Canada for Canadian federal income tax purposes by virtue of being incorporated under the laws of a province of Canada. Accordingly, we will be subject to Canadian taxation on our worldwide income, in accordance with the rules in the Income Tax Act (Canada) (the "Tax Act") generally applicable to corporations resident in Canada. Notwithstanding that we will be deemed to be a resident of Canada for Canadian federal income tax purposes, we are treated as a U. S. corporation for U. S. federal income tax purposes, pursuant to Section 7874 (b) of the Code, and the U. S. Treasury Regulations promulgated thereunder. Accordingly, we will be subject to a number of significant and complicated U. S. federal income tax consequences as a result of being treated as a U. S. domestic corporation for U. S. federal income tax purposes and will be subject to taxation on our worldwide income both in Canada and the United States, which could have a material adverse effect on our financial condition and results of operations. Dispositions of common shares may be subject to Canadian tax and will be subject to United States tax, and dividends on common shares will be subject to Canadian and / or United States taxes. Dispositions of common shares will not be subject to Canadian tax, unless the common shares constitute "taxable Canadian property" (as defined in the Tax Act) of a holder of the common shares that is a non- resident of Canada for purposes of the Tax Act. Such holders whose common shares may constitute taxable Canadian property should consult their own tax advisors. In addition, dispositions of common shares by U. S. Holders (as defined below) will be subject to U. S. tax, and certain dispositions of common shares by Non- U. S. Holders (including if we are treated as a U. S. real property holding corporation ("USRPHC")) will be subject to U. S. tax, as described below. It is currently not anticipated that we will pay any dividends on the common shares in the foreseeable future. However, to the extent dividends are paid on the common shares, dividends received by shareholders who are residents of Canada for purposes of the Tax Act (and Non- U. S. Holders for purposes of the Code) will be subject to U. S. withholding tax. Any such dividends may not qualify for a reduced rate of withholding tax under the Canada- United States income tax treaty (the "Treaty"). In addition, a Canadian foreign tax credit or a deduction in respect of

such U. S. withholding taxes paid may not be available. Dividends received by U. S. Holders will not be subject to U. S. withholding tax but will be subject to Canadian withholding tax, subject to any reduction in the rate of withholding under the Treaty. Any such dividends may not qualify for a reduced rate of withholding tax under the Treaty. Dividends paid by us will be characterized as U. S. source income for purposes of the foreign tax credit rules under the Code. Accordingly, U. S. Holders may not be able to claim a credit for any Canadian tax withheld unless, depending on the circumstances, they have other foreign source income that is subject to a low or zero rate of foreign tax. Dividends received by shareholders that are neither Canadian nor U. S. shareholders will be subject to U. S. withholding tax and will also be subject to Canadian withholding tax. These dividends may not qualify for a reduced rate of U. S. withholding tax under any income tax treaty otherwise applicable to a shareholder of ours, subject to examination of the relevant treaty. These dividends may, however, qualify for a reduced rate of Canadian withholding tax under any income tax treaty otherwise applicable to a shareholder of ours, subject to examination of the relevant treaty. For purposes hereof, a "U. S. Holder" is a beneficial holder of common shares who or that, for U. S. federal income tax purposes, is: • an individual who is a United States citizen or resident of the United States; • a corporation or other entity treated as a corporation for U. S. federal income tax purposes created in, or organized under the laws of, the United States, any state thereof or the District of Columbia; • an estate the income of which is includible in gross income for U. S. federal income tax purposes regardless of its source; or • a trust (A) the administration of which is subject to the primary supervision of a U. S. court and which has one or more United States persons (within the meaning of the Code) who have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable U. S. Treasury Regulations to be treated as a U. S. person. For purposes hereof, a "Non- U. S. Holder" means a beneficial owner of common shares that is not a U. S. Holder (except that, with respect to an entity (or other arrangement taxable as a partnership for U. S. federal income tax purposes), a "Non- U. S. Holder" refers to any partner in such partnership that is not a U. S. Holder as defined above). As a U. S. domestic corporation for U. S. federal income tax purposes, ~~the taxation of any gain realized by our Non- U. S. Holders upon a disposition of our common shares generally depends~~ **will not be subject to U. S. federal income tax unless: • the gain is effectively connected with a trade or business of the Non- U. S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a United States permanent establishment or fixed base of the Non- U. S. Holder); • the Non- U. S. Holder is an individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition, and certain other conditions are met; or • we are or have been** classified as a USRPHC for U. S. federal income tax purposes **at any time during the shorter of the five-year period ending on the date of disposition or the Non- U. S. Holder's holding period for such common shares disposed of**. We believe that we presently are not a USRPHC and do not presently anticipate that we will become a USRPHC. However, because this determination is made from time to time and is dependent upon a number of factors, some of which are beyond our control, including the value of our assets, there can be no assurance that we will not become a USRPHC. If we ultimately are determined by the United States Internal Revenue Service ("IRS"), to constitute a USRPHC, our Non- U. S. Holders may be subject to U. S. federal income tax on any gain associated with the disposition of the common shares. We may incur significant tax liabilities ~~under as a result of~~ Section 280E of the Code **that could negatively impact the results of our operations**. Section 280E of the Code **generally prohibits businesses from deducting certain or claiming tax credits with respect to expenses associated with paid or incurred in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of Schedule I and II of the CSA) which are prohibited by federal law or the law of any state in which such trade or business is conducted. The application of Section 280E of the Code generally causes such businesses to have an effective tax rate in the United States that is significantly higher than the rate typically applicable to businesses in other industries**. The IRS has invoked Section 280E of the Code in tax audits against various businesses in the United States, **even when the business activities were that carry on certain drug sales that are** permitted under applicable state laws. Although the IRS issued a clarification ~~allowing of Section 280E of the Code that allows~~ the deduction of certain expenses, the scope of such items is interpreted very narrowly and the bulk of operating costs and general administrative costs are not **permitted** permissible deductions. As a result, we will have an effective tax rate in the U. S. significantly higher than the rate typically applicable to **be deducted in addition** 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 **courts, in response to challenges of** these courts **restrictions by taxpayers**, will issue an interpretation of Section 280E of the Code favorable to our businesses. 88