Risk Factors Comparison 2025-03-17 to 2024-03-19 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Financial Position and Need for Additional Capital ● Since we have no revenue from product sales and do not expect any revenue from product sales for at least three or four years, we will likely need additional funding to continue our clinical development activities and other operations, which may not be available to us on acceptable terms, or at all. ● We have incurred substantial losses since our inception and expect to continue to incur substantial losses for at least three or four years and may never become profitable, or if achieved, be able to sustain profitability. ~~● Adverse developments with respect to the stability of financial institutions we do business with, or unstable banking, credit and / or capital market conditions generally, or the perception thereof, could adversely affect our ability to access our cash on deposit with financial institutions, obtain additional financing, or meet our liquidity requirements.~~ Risks Related to Governmental and Regulatory Compliance and Approvals ● The regulatory approval process is expensive, time- consuming and uncertain and may prevent us or any future partner or collaborator from obtaining approvals for the commercialization of DM199 or any future product candidate. ● Any product candidate for which we or any future partner or collaborator obtains marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with the product candidate. Risks Related to Our Reliance on Third Parties ● We rely on third parties to support the planning, execution and / or monitoring of our preclinical and clinical trials, and their failure to perform as required could cause delays in completing our product development and substantially harm to our business. ● We rely on contract manufacturers over whom we have limited control. ● Future development collaborations are expected to be important to us. Risks Related to Intellectual Property ● We could lose important intellectual property rights that we currently license from a third party if we fail to comply with our obligations under the license agreements under which we license intellectual property rights from this third party or otherwise experience disruptions to our business relationships with our licensor. ● We may be unable to adequately protect our technology and enforce our intellectual property rights. ● We or a future partner may require additional third- party licenses to effectively develop, manufacture and commercialize DM199, or any future product candidate, and such licenses might not be available on commercially acceptable terms, or at all. ● Changes in patent law and its interpretation could diminish the value of our patents. ● Intellectual property litigation may be expensive, time consuming and may cause delays in the development, manufacturing and commercialization of DM199 or any future product candidate. Risks Related to Human Capital Management ● We rely heavily on the capabilities and experience of our key executives, clinical personnel and advisors and the loss of any of them could affect our ability to develop DM199 or any future product candidate. ● We will likely need to expand our operations and increase the size of our Company and we may experience difficulties in managing our growth. Risks Related to the Future Commercialization of DM199 or Any Future Product Candidate ● The successful commercialization of DM199 or any future product candidate, if approved, will depend on achieving market acceptance and we may not be able to gain sufficient acceptance to generate significant revenue. ● If we fail to obtain coverage and adequate reimbursement for DM199 or any future product candidate, its revenue- generating ability will be diminished and there is no assurance that the anticipated market for the product will develop or be sustained. ● We or any future partner will likely face competition from other biotechnology and pharmaceutical companies, many of which have substantially greater resources than us. ● Our DM199 product candidate may face competition sooner than expected. **● Our estimates of the market opportunity for our DM199 product candidate are based on a number of assumptions and may prove to be inaccurate.** Risks Related to Our Common Shares ● Our common share price has been volatile and may continue to be volatile. ● We do not have a history of a very active trading market for our common shares. ● We may issue additional common shares resulting in share ownership dilution ~~. ● If~~ **, and if** there are substantial sales of our ~~common~~ shares or the perception that such sales may occur, the market price of our ~~common~~ shares could decline. Risks Related to Our Jurisdiction of Organization ● We are governed by the corporate laws of British Columbia, which in some cases have a different effect on shareholders than the corporate laws in effect in the United States. ● We were classified as a " passive foreign investment company " **(PFIC)** for **our 2024, 2023 and** 2022 and ~~2023~~ **certain other years** and may continue to be **so classified** in future taxable years, which may have adverse U. S. federal income tax consequences for U. S. shareholders and adversely affect the level of interest in our common shares by U. S. investors. **Any common shareholder who held our shares in years when we were classified as a PFIC will be subject to special reporting rules in order to avoid adverse PFIC tax consequences. Even if we subsequently no longer qualify as a PFIC in a future taxable year, shareholders will still be subject to the PFIC rules for shares acquired in years when we were a PFIC unless a so- called " purging election " is made, as described below.** Risks Related to Our ~~ReMEDy2 Trial~~ **Business Model Our business model assumes we will generate revenue by , among other activities, marketing or out- licensing the product candidates we develop. Since our product candidates are in various stages of development and we have no products approved for commercialization, there is a limited amount of information about us upon which you can base an evaluation of our business and prospects. None of our product candidates have completed clinical development; and therefore, we have no product candidates approved for commercialization and thus have not begun to market or generate revenues from the commercialization of any product candidates. Because no product candidate has completed clinical development and been approved for commercialization, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. For example, to execute our business plan, we will need to successfully: ● Demonstrate safety and efficacy of our product candidates in human clinical studies; ● Complete manufacturing**

development activities relating to our DM199 product candidate for the treatment of AIS or PE or any other indications we decide to purse and any other product candidates we choose to develop; ● Receive FDA approval and / or approval from similar foreign regulatory bodies; ● Gain market acceptance for the commercialization of any products we develop and have not out- licensed such rights; ● Obtain reimbursement by commercial and / or government payors at a rate that permits commercial viability; ● Develop and maintain successful strategic relationships with suppliers, distributors and commercial licensing partners; ● Build, maintain, and protect an adequate intellectual property portfolio; and ● Manage our spending and cash requirements as our expenses are anticipated to increase in the near term as we ramp up enrollment in our clinical trials and if we add new indications for DM199 and other product candidates and conduct additional preclinical and clinical trials. If we are unsuccessful in accomplishing these objectives, or in making sufficient progress toward these objectives, we may not be able to develop and maintain successful strategic relationships, raise capital, and continue our operations. We may need to establish relationships with strategic partners to fully develop our product candidates and, if approved, market any product candidates that are approved. Our business strategy includes securing license agreements and collaborations with other pharmaceutical and biotech companies to support the development of DM199 for various indications. We do not possess all of the financial resources necessary to complete the development of and commercialize our product candidates, if and when they are approved. Unless we expand our own internal sales and marketing capability, we will likely need to make arrangements with other strategic partners to commercialize any product candidates that may be approved. We may not be able to attract such partners, and even if we are able to enter into such partnerships, the terms may be less favorable than anticipated. Further, entering into partnership agreements may limit our commercialization options and would require us to share revenues and profits with our partners. If we do not find appropriate partners, or if such future agreements are not successful, our ability to commercialize products could be adversely affected. Even if we are able to find collaborative partners, the overall success of the commercialization of product candidates in those programs will depend largely on the efforts of those other parties and may be beyond our control and our licensees may elect to assume greater control over these programs. In addition, in the event we pursue our commercialization strategy through collaboration or licenses to third parties, there are a variety of technical, business and legal risks, including, among others: ● We may be unable to control the amount and timing of resources that our collaborators may be willing or able to devote to the commercialization of our product candidates including to their marketing and distribution efforts; and ● Disputes may arise between us and our collaborators that result in the delay or termination of the commercialization of our product candidates or that result in costly litigation or arbitration that diverts our management' s resources. The occurrence of any of the above events or other related events could impair our ability to generate revenues and harm our business, prospects, operating results and financial condition. Risks Related to Our Current and Future Clinical Trials and DM199 Product Candidate We have had and may continue to have difficulty ~~engaging clinical trial sites for, or~~ enrolling patients in ~~,~~ our ReMEDy2 trial or we may experience other clinical testing delays or setbacks, which would delay our ability **or the ability of a future partner** to obtain regulatory approval for DM199 to treat AIS and commercialize it, ~~or partner with a third party to obtain regulatory approval for or commercialization of DM199 to treat AIS,~~ which would substantially harm our business and prospects. **Our ReMEDy2 trial is a Phase 2 / 3, adaptive design, randomized, double- blind, placebo- controlled trial that is intended to enroll approximately 300 patients at up to 100 sites globally.** We have had and may continue to have difficulty ~~engaging clinical trial sites for, and~~ enrolling patients in **our** ~~, the~~ ReMEDy2 trial, which could delay ~~the~~ **further** completion of the trial **or even jeopardize the viability of the trial** . **We believe these enrollment difficulties may be due, in part, to hospital and medical facility staffing shortages; inclusion / exclusion criteria in the study protocol;** ~~Concerns~~ **concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility; concerns** regarding the prior clinically significant hypotension events and circumstances surrounding the clinical hold which was lifted in June 2023 ~~may add~~ **; use of artificial intelligence and telemedicine which have enabled smaller hospitals** to **retain AIS patients not eligible for mechanical thrombectomy instead of sending** these ~~difficulties~~ **patients to the larger stroke centers which are more likely to be sites in our trial; and competition for research staff and trial subjects due to other pending stroke and neurological trials. While we have taken several actions to mitigate the impact of these factors adversely affecting our ReMEDy2 trial enrollment rate, such as significantly expanding our internal clinical team and bringing in- house certain trial activities, adopting procedures to support study sites and potential participants as needed, globally expanding the trial, and making certain changes to the study protocol, no assurance can be provided that these actions will lead to increased enrollment. In addition, these actions also involve their own risks** . In addition, it is possible that we may experience other clinical testing delays or setbacks, which would further delay ~~the~~ completion of the ReMEDy2 trial. ~~Our product~~ **Product** development costs ~~will~~ **typically** increase **with** ~~if we experience~~ delays in clinical testing. Significant clinical trial delays could not only extend the time period for obtaining regulatory approval of DM199 to treat AIS **and increase our costs** , but also shorten any periods during which we or a future partner may have the exclusive right to commercialize DM199 to treat AIS or allow our competitors to bring competitive products to market before us, which would ~~impair~~ **adversely affect** the ability to successfully commercialize DM199 and may harm our **business, prospects, operating results and** financial condition ~~, results of operations and prospects~~ . The ReMEDy2 trial may be delayed for a number of reasons, including ~~among others~~ **without limitation those described above as well as the following** : ● ~~concerns regarding~~ **sites waiting for internal approvals of** the **most recently revised protocol for** ~~prior clinically significant hypotension events and circumstances surrounding~~ the **trial** ~~clinical hold which was lifted in June 2023~~ ; ● patients choosing to participate in competing clinical trials or not at all; ● scheduling conflicts with participating clinicians and clinical sites; ● complexities in setting up and coordinating with sites that are located outside the United States and additional risks involved in a trial that is being conducted, in part, outside the United States; ● suspension or termination of the ReMEDy2 trial by regulators for any reason, including concerns

about patient safety or failure of our contract manufacturers to comply with current Good Manufacturing Practices (cGMP) requirements; ● any changes to our manufacturing process that may be necessary or desired which affect our ability to produce adequate or timely clinical drug supply; ● delays or failure to obtain clinical drug supply of DM199 from contract manufacturers necessary to conduct clinical trials; ● our DM199 product candidate demonstrating a lack of safety or efficacy at the planned interim analysis of the ReMEDy2 trial; ● patients failing to enroll or complete the ReMEDy2 trial at the rates and within the timelines we expect due to dissatisfaction with the treatment, side effects or other reasons; ● clinical investigators not performing the ReMEDy2 trial on their anticipated schedule, dropping out of a trial or employing methods not consistent with the clinical trial protocol and regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner; ● inspections of our clinical trial sites by regulatory authorities, Institutional Review Boards (IRBs) or ethics committees finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of another clinical hold on the IND for our ReMEDy2 trial; or ● public health crises, epidemics or pandemics, such as COVID- 19, which may adversely impact our ability to **continue to** engage and activate clinical trial sites, recruit or enroll subjects for our ReMEDy2 trial or any future trial and obtain the requisite staffing for our ReMEDy2 trial or any future trial. Our product development costs may ~~also~~ increase if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend trial protocols or alter our manufacturing processes to reflect these changes. Amendments typically require us to resubmit our trial protocols to **the FDA and other** regulatory authorities and IRBs or ethics committees **,** for re- examination, which may impact the cost, timing or successful completion of our ReMEDy2 trial. Delays or increased product development costs or any of these events would likely have a material adverse effect on our business, **prospects, operating results and** financial condition ~~, and prospects. The COVID- 19 pandemic adversely impacted hospital and medical facilities, causing, among other things, staffing shortages, which have previously delayed site activations and patient enrollments in our ReMEDy2 trial and could continue to adversely affect the trial. COVID- 19 has had, and may continue to have, a severe effect on the clinical trials of many drug candidates, including our ReMEDy2 trial. Prior to the clinical hold of our ReMEDy2 trial, we experienced challenges with engaging and activating clinical trial sites. We believe this was due primarily to clinical staff shortages resulting from layoffs and employee burnout, the reallocation of clinical nurses to COVID- 19 care, particularly during surges in COVID- 19 cases, a loss of study coordinators resulting from budget constraints and COVID- 19 vaccination requirements. Hospital study sites have been especially impacted by these factors. Additionally, prior to the clinical hold of our ReMEDy2 trial, we experienced slower than expected enrollments in the trial due to these factors and patient concerns related to visiting clinical trial sites or being visited by clinical study nurses. In an effort to mitigate the impact of these factors, we have worked with our contract research organization to develop alternative procedures to support study sites and potential participants as needed. We intend to continue to monitor the results of these efforts or implement additional actions to mitigate the impact of these factors on our ReMEDy2 trial. It is also possible that these efforts may draw our employees away from their core responsibilities and create additional expenses, which may adversely affect our business and results of operations. Note however that these efforts may not be effective if patients are unwilling to enroll in our ReMEDy2 trial. We anticipate that COVID- 19, and variants of COVID- 19, will likely continue to adversely affect our ability to initiate new clinical trial sites and recruit or enroll subjects, and we cannot provide any assurance that we will be able to resolve these issues. Although the severity of the COVID- 19 virus has decreased significantly during the past two years, the extent to which COVID- 19 may impact our ReMEDy2 trial will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the emergence of new variants, the duration and severity of each variant, and the effectiveness of actions to contain, treat and prevent COVID- 19, including the availability, effectiveness and acceptance of vaccines and vaccine booster shots. The resurgence of COVID- 19 caused by any new variants in the future or another pandemic could cause us to experience continued and / or additional disruptions that could severely impact our ReMEDy2 trial, as well as our business~~ . The adaptive design of our ReMEDy2 trial could result in the trial being required to enroll more patients than anticipated, **which would** ~~increasing~~ **increase** the time and costs to complete the trial ~~, which may require additional funding that may not be available to us on favorable terms or at all~~ . Our ReMEDy2 trial is ~~currently targeted~~ **an adaptive design trial intended** to enroll approximately ~~350~~ **300** patients ~~at up to 100 sites globally~~ . ~~However, with~~ **The adaptive design component includes an interim analysis by our independent data safety monitoring board after** the **first 200 participants have completed the trial. Based on the results of the interim analysis, the study may be stopped for futility or a new total sample size may be determined, ranging between 300 and 728 participants, according to a pre- determined statistical analysis plan. Because of the ReMEDy2** trial' s adaptive design, it is possible that the number of ~~patients~~ **participants** required to complete the trial may increase significantly **from the 300 patients we are currently targeting** . If we are required to enroll more ~~patients~~ **participants** than currently anticipated, it will increase the time and costs to complete the trial, which may result in a need for additional funding that may not be available to us on acceptable terms, or at all. **The expansion of our DM199 clinical development program into PE involves certain risks related to timing, regulatory approvals, costs and enrollment, and the fact that the PE trial is investigator- sponsored, raises additional risks. We are currently financially supporting the conduct of a Phase 2 open- label, single center, single- arm, safety and pharmacodynamic, proof- of- concept, investigator- sponsored study of DM199 for the treatment of PE at the Tygerberg Hospital, Cape Town, South Africa. This study may enroll up to 90 women with PE and potentially an additional 30 women with fetal growth restriction may be evaluated. Part 1A top line study results are anticipated in the second quarter of 2025 and are intended to demonstrate whether DM199 is safe and lowers maternal blood pressure. Additionally, patients with early onset PE will be evaluated for improvements in uterine artery dilation, a sign that DM199 is a potentially disease modifying therapy. The expansion of our DM199 clinical development program into PE and the progress of that program may not occur on the anticipated timeline or at all. In addition, the Phase 2 PE trial may cost us more than we anticipate. Additionally, because the trial is investigator- sponsored, we have**

less control over the timing and costs of the study and the ability to recruit trial participants than if we conducted the study with our own personnel. There is no guarantee that our physician collaborators will devote adequate time and resources to perform this study and / or maintain adequate clinical trial information regarding our product candidate. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to the study protocol, or fail to act in accordance with regulatory requirements or our agreement with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then the current PE trial or future clinical trials may be extended or delayed with additional costs incurred, or our data may be rejected by applicable regulatory agencies. Any of these risks could adversely impact our business, prospects, operating results ns and financial position, including our ability to raise additional financing, if and when needed. DM199 and any other product candidates we choose to develop may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if granted. As with most pharmaceutical products, DM199 and any future product candidates could be associated with side effects or adverse events, which can vary in severity and frequency. Although the only DM199 related adverse events that have occurred to date in our clinical trials have been constipation, injection site reaction, nausea, headache, flushing and three unexpected instances of clinically significant, but transient, hypotension (low blood pressure), side effects or adverse events associated with the use of DM199, or any future product candidates, may be observed at any time during clinical development. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the Institutional Review Boards, or independent ethics committees at the institutions in which our studies are conducted, or the data safety monitoring board, could suspend or terminate our clinical trials, similar to when the FDA imposed a clinical hold on our current ReMEDY2 trial in 2021, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may be required to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may prevent us, or any future partner from achieving or maintaining market acceptance of the affected product candidate and may harm our business, prospects, operating results and financial condition. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, toxicity or other safety issues, and could require us to perform additional studies, including preclinical studies, or halt development of DM199 or any future product candidates, or expose us to product liability lawsuits that would likely harm our business. There can be no assurance that we will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or any other regulatory authority in a timely manner, if ever, which could harm our business, prospects, operating results and financial condition. We are required by the FDA and other comparable foreign regulatory authorities to report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA other comparable foreign regulatory authorities could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products, halting our clinical trials or delay in approval or clearance of future product candidates. We face the risk of product liability claims, which could exceed our insurance coverage, deplete our cash resources and lead to clinical trial delays. A risk of product liability claims, and related negative publicity, is inherent in the development of human therapeutics. We are exposed to the risk of product liability claims alleging that use of DM199, or any future product candidate, caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or, if approved, commercial sale of a product candidate. Such claims may be made directly by patients involved in clinical trials of our product candidate, by consumers, healthcare providers or by individuals, organizations or companies selling our products, if approved. Product liability claims can be expensive to defend, even if the product or product candidate did not actually cause the alleged injury or harm, and could lead to clinical trial delays and could negatively impact existing or future trial enrollment. Insurance covering product liability claims is expensive. To protect against potential product liability risks, we carry product liability insurance coverage at a level we deem appropriate based upon the current safety profile of DM199 and our stage of development. We may choose or find it necessary to increase our insurance coverage in the future; however, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and otherwise have a material adverse effect on our business, operating results and financial condition. If we are unable to maintain product liability insurance required by third parties, certain agreements, such as those with clinical trial sites, contract research organizations and other supporting vendors, would be subject to termination, which could have a material adverse impact on our operations. Some of our agreements with third parties require, and in the future will likely require, us to maintain product liability insurance in at least certain specified minimum amounts. If we cannot maintain acceptable amounts of coverage on

commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations. The PE trial is being conducted in South Africa and we are in the process of globally expanding our ReMEDy2 trial to countries outside the United States, raising additional international risks, which could materially adversely affect our business. The PE trial is currently being conducted in South Africa and we are in the process of expanding our ReMEDy2 trial to certain non- U. S. countries, including Canada, Australia, Georgia, United Kingdom and certain countries in the European Union. In addition, we plan to seek regulatory approval of DM199, or any future product candidates, outside of the United States. Accordingly, we are subject to risks related to operating in foreign countries including, among others: ● different standards of care in various countries that could complicate the design of our clinical trials and / or the evaluation of our product candidates; ● compliance with differing regulatory requirements for drug approvals; ● availability of different competitive drugs or therapies indicated to treat the indications for which our product candidates are or will be developed; ● compliance with different United States and foreign drug import and export rules; ● the imposition of U. S. or international sanctions against a country, company, person or entity where or with whom we are conducting clinical studies that would restrict or prohibit continued development in that country or with that company, person or entity; ● compliance with the Foreign Corrupt Practices Act and other anti- corruption and anti- bribery laws; ● foreign taxes, including withholding of payroll taxes; ● foreign currency exchange rate fluctuations, which could result in increased operating expenses and other obligations incident to performing clinical trials in another country; ● difficulties in managing and staffing international operations and increases in infrastructure costs, including legal, tax, accounting, and information technology; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential liability resulting from development work conducted by foreign partners or collaborators; ● delays and interruptions in delivering study drug and related supplies to clinical trial sites; ● interruptions in our development resulting from natural disasters or geopolitical actions, including war, such as the current war between Russia and Ukraine and the conflict between Israel and Hamas and in the Middle East, and terrorism or systems failure, including cybersecurity breaches; and ● compliance with evolving and expansive international data privacy laws, such as the European Union General Data Protection Regulation. It is possible that the FDA and comparable foreign regulatory authorities may not accept trial data from countries located outside the United States. The PE trial is being conducted in South Africa and we are in the process of globally expanding our ReMEDy2 trial to countries outside the United States. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the United States or another jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice (GCP) regulations; and (iii) the FDA, or comparable foreign regulatory authority, is able to validate the data through an on- site inspection or other appropriate means. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional participants or trials, which would be costly and time- consuming and delay regulatory approval and commercialization of our DM199 product candidate. Data from the investigator- sponsored PE trial, which we expect in the second quarter of 2025 and thus earlier than data from our ReMEDy2 trial, may adversely affect our ReMEDy2 trial, which could adversely impact our business, prospects, operating results and financial position and harm our ability to raise additional financing, if and when needed. Our drug candidate, DM199, is currently in clinical development in two areas, AIS and PE. We anticipate Part 1A topline study results for the Phase 2 PE clinical trial in the second quarter of 2025. Part 1A topline study results are intended to demonstrate whether DM199 is safe for PE patients, lowers blood pressure, and, in early on- set patients, dilates intrauterine arteries to increase placental blood flow. The results from Part 1A of the study may not be consistent with the safety results from our prior trials of DM199 in humans. If the Part 1A topline study results are inconsistent, incomplete or otherwise demonstrate that DM199 is not safe or does not lower blood pressure, our current ReMEDy2 clinical trial of DM199 for the treatment of AIS may be adversely affected. Should this occur, we may be required to repeat clinical or non- clinical studies, our clinical development plans may be significantly delayed, and we may incur additional costs, which could adversely impact our business, prospects, operating results and financial position. Adverse results from the Part 1A topline study also could adversely affect our ability to raise additional financing, if and when needed. Interim, " topline " and preliminary results from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, topline or preliminary results from our clinical trials. We anticipate Part 1A topline study results for the Phase 2 PE clinical trial in the second quarter of 2025. Interim results from clinical trials are subject to the risk that one or more of the reported clinical outcomes may materially change as participant enrollment continues and more participant data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, topline or interim data and final data could significantly harm our business and prospects and may cause the trading price of our common shares to fluctuate significantly. We also make estimations, calculations and conclusions as part of

our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Further, others, including regulatory authorities, may not accept or agree with our estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business and prospects. If our ReMEDy2 trial fails to adequately demonstrate the safety and efficacy of DM199 to treat AIS **or if the PE trial fails to adequately demonstrate the safety and initial signs of efficacy of DM199 to treat PE** , we will not be able to obtain ~~the~~ **required** regulatory approvals ~~required to market and commercialize the product~~ , which would substantially harm our business ~~and~~ **,** prospects **and financial condition** . Before obtaining marketing approval from **the FDA and other comparable foreign** regulatory authorities for the sale of DM199 to treat AIS **or the approval to continue testing DM199 as a treatment for PE** , we must demonstrate the safety and efficacy of DM199 to treat AIS **or PE** to a level acceptable to the FDA or similar regulatory bodies **in** other jurisdictions. Clinical testing is expensive ~~and~~ **,** difficult to design and implement, can take many years to complete **,** and has uncertain outcomes. The outcome of ~~preclinical trials and~~ early clinical trials may not predict the success of later clinical trials, and the interim results of ReMEDy2 **and the results of the PE trial** may not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, including the emergence of undesirable side effects, notwithstanding promising results in earlier trials. We do not know whether our ReMEDy2 trial by itself will demonstrate adequate efficacy and safety to support regulatory approvals to market DM199 to treat AIS in the United States, or in any **other** jurisdiction, or that a second confirmatory trial will be required. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. In addition, the patient ~~populations~~ **population** in our **ReMEDy2** ~~current clinical~~ trial ~~for DM199, and anticipated future clinical trials for DM199,~~ often have co- morbidities that may cause severe illness or death, which may be attributed to DM199 in a manner that negatively affects the safety profile of our DM199 product candidate. If the results of our ReMEDy2 trial are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance or if there are unanticipated safety concerns or adverse events that emerge during the ReMEDy2 trial **, the PE trial** or other clinical trials, such as the events that caused the FDA to place the prior clinical hold on the IND for our ReMEDy2 trial, we may be prevented from or delayed in obtaining marketing approval, and even if we obtain marketing approval, any sales of DM199 for the treatment of AIS may be limited. We may be required to suspend, repeat or terminate our ~~ReMEDy2 trial or other~~ clinical trials if they are deemed not conducted in accordance with regulatory requirements, the results are negative or inconclusive **,** or the trial is not well designed. Clinical trials must be conducted in accordance with the FDA' s current Good Clinical Practice (cGCP) requirements, or ~~analogous~~ **comparable** requirements of applicable foreign regulatory authorities, and ~~designed to~~ provide statistically significant evidence predictive of patient benefit. Clinical trials are subject to oversight by the FDA ~~,~~ **and** other foreign governmental agencies **,** and IRBs or ethics committees at the trial sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable ~~cGMP~~ **GMP requirements** . Clinical trials may be suspended by us or by the FDA, other foreign regulatory authorities **,** or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including: ● deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or trial protocols; ● deficiencies in the clinical trial operations or trial sites; ● unforeseen adverse side effects or the emergence of undue risks to trial subjects; ● deficiencies in the trial design necessary to demonstrate efficacy; ● **in the case of interim analyses,** the product candidate may not appear to offer benefits over current therapies; or ● the quality or stability of the product candidate may fall below acceptable standards. The design and implementation of clinical trials is a complex process. As a Company, we have limited experience designing and implementing clinical trials. We may not successfully or cost- effectively design and implement clinical trials that achieve our desired clinical endpoints. A clinical trial that is not well designed or that yields unforeseen adverse side effects or undue risks to trial subjects may delay or even prevent initiation of the trial, can lead to increased difficulty in site activations and enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the trial results or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third party payers. Additionally, a trial that is not well designed or that yields unforeseen adverse side effects or undue risks to trial subjects could be delayed and more expensive than it otherwise would have been, or we may incorrectly estimate the costs to complete the clinical trial, which could lead to a shortfall in funding. We can provide no assurance that our ReMEDy2 trial **, the PE trial** or any other clinical trial conducted **or sponsored** by us has been or will be designed and implemented successfully or achieve its desired clinical endpoints. Our prospects depend on the clinical and commercial success of our DM199 product candidate ~~which is in the clinical stage of development~~ . We are highly dependent on the success of DM199 and we **, or a future partner,** may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate. To date, we have expended significant time, resources **,** and effort on the development of DM199, including conducting preclinical and clinical trials, for the treatment of AIS and ~~CRD~~ **cardio renal disease** . DM199 requires significant additional

clinical testing and investment prior to seeking marketing approval. A commitment of substantial resources by ~~ourselves~~ **us** and any potential partner or collaborator to continue to conduct the clinical trials for DM199 will be required to obtain required regulatory approvals and successfully commercialize this product candidate. Although we intend to study the use of DM199 to treat multiple diseases, we have no other product candidates in our current clinical development pipeline, with the exception of our new ~~product~~ **second** candidate, DM300, which is in the early, preclinical stage of development and is intended to treat other inflammatory diseases, such as acute pancreatitis. ~~Our~~ **The** ability **of us or a future partner** to generate revenue from product sales and to achieve commercial success with DM199 will depend almost entirely on our ability to demonstrate sufficient safety and efficacy to obtain regulatory approval for DM199. We may fail to complete required clinical trials successfully and not be able to obtain regulatory approvals or commercialize DM199. Competitors may develop alternative products and methodologies to treat the diseases or indications that we are pursuing, thus reducing or eliminating the anticipated competitive advantages of DM199. We do not know whether any of our product development efforts will prove to be effective, meet applicable regulatory standards required to obtain **marketing** ~~the requisite regulatory approvals~~ **approval**, be capable of being manufactured at a reasonable cost **,** or be successfully marketed. DM199 is not expected to be commercially viable for at least three or four years. In addition, although the only ~~significant~~ **DM199 related** adverse events that have occurred to date in our clinical trials have been **constipation, injection site reaction, nausea, headache and** three unexpected instances of ~~transient,~~ clinically significant **, but transient**, hypotension (low blood pressure), it is possible that DM199 may be observed to cause undesirable side effects ~~. Results of early preclinical and clinical research may not be indicative of the results that will be obtained in later stages of clinical research~~. If regulatory authorities do not approve DM199 for the treatment of AIS **, PE** or any other indications, or if we fail to maintain regulatory compliance, we **, or a future partner,** would be unable to commercialize DM199 and our business ~~and~~ **, prospects, operating** results ~~of operations~~ **and financial condition** would be harmed. If we do succeed in developing viable products from DM199, we will face many potential future obstacles, such as the need to develop or obtain manufacturing, sales and marketing **,** and distribution capabilities ~~. The clinical success and commercial potential of our DM199 product candidate will depend on a number of factors~~ **, if we do not partner with** ~~many of which are beyond our control. The clinical success and commercial potential of our DM199 product candidate to treat AIS or any other indication will depend on~~ a ~~number of factors, many of which are beyond our control, including, among others: ● the timely initiation, continuation and completion of clinical trials, including our Phase 2 / 3 ReMEDy2 trial and future clinical trials for DM199, which will depend substantially upon requirements for such trials imposed by the FDA and other regulatory agencies and bodies; ● our ability to demonstrate the safety and efficacy of DM199 to the satisfaction of the relevant regulatory authorities and / or~~ third ~~-~~ party ~~payers; ● whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to or after approval to market our DM199 product candidate; ● the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, as well as achieving adequate pricing and reimbursement determinations; ● the ability to successfully commercialize DM199, if approved by the FDA or foreign regulatory authorities, whether alone or in collaboration with others; ● our ability and the ability of third- party manufacturers to manufacture the quantities of DM199, with quality attributes necessary to meet regulatory requirements, sufficient to meet anticipated demand and at a cost that allows us or a future partner to achieve profitability; ● acceptance of DM199, if approved, as safe and effective by patients and healthcare providers; ● the achievement and maintenance of compliance with all regulatory requirements applicable to DM199 by us and our third- party manufacturers and supporting vendors; ● the maintenance of an acceptable safety profile of DM199 following any approval; ● the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competitive treatments; ● our ability~~ to provide ~~approved product with an acceptable patient administration method; ● our ability or the ability of a future partner to successfully enforce our intellectual property rights for DM199; and ● our ability to avoid or succeed in defending any third- party patent interference or patent infringement claims. In addition, because the plastic bags we use in the IV administration of DM199 are made of PVC, certain countries have banned or limited the use of PVC in a manner that, unless we are able to find an alternative, may limit the salability of DM199 in certain countries, thereby decreasing our worldwide market opportunity. No assurance can be provided that we will ever be able to achieve profitability through the sale of, or royalties from, our DM199 product candidate. If we or any future partners or collaborators are not successful in obtaining approval for and commercializing DM199, or are delayed in completing those~~ **these functions** ~~efforts, our business and operations would be substantially harmed~~. Since we currently have no revenue from product sales and do not expect any revenue from product sales for at least three or four years, we will need additional funding to continue our clinical development activities and other operations, which may not be available to us on acceptable terms, or at all. We expect we will need substantial additional capital to further our R & D activities, planned clinical trials and regulatory activities and to otherwise develop our DM199 product candidate to a point where it may be commercially sold. We expect our current cash resources of $ ~~52~~ **44** . ~~9~~ **1** million in cash, cash equivalents and marketable securities as of December 31, ~~2023~~ **2024** to be sufficient to allow us to continue our Phase 2 / 3 trial in patients with AIS **, the PE trial** and to otherwise fund our planned operations for at least the next 12 months from the date of issuance of the financial statements included in this report. However, the amount and timing of our future funding requirements will depend on many factors, including, among others: ● the rate of progress in the development of and the conduct of clinical trials with respect to DM199 or any future product candidates; ● the timing and results of our ongoing development efforts, including in particular our Phase 2 / 3 ReMEDy2 **trial and the PE** trial; ● the costs of our development efforts, including the conduct of clinical trials with respect to DM199 or any future product candidates; ● the costs associated with identifying additional product candidates and the potential expansion of our current development programs or potential new development programs; ● the costs necessary to obtain regulatory approvals for DM199 or any future product candidates; ● the costs of developing and validating manufacturing processes for DM199 or any future product candidates; ● the costs associated with being a U. S. public reporting company with shares listed on The Nasdaq Capital Market; ● the costs we incur in the filing, prosecution, maintenance and defense of our

intellectual property; and ● the costs related to general and administrative support. We may require significant additional funds earlier than we currently expect, and there is no assurance that we will not need or seek additional funding prior to such time. We may elect to raise additional funds even before we need them if circumstances or market conditions for raising additional capital are favorable. Since our inception, we have financed our operations primarily from public and private sales of equity securities, the exercise of warrants and stock options, interest income on funds available for investment and government grants and tax incentives. We expect to continue this practice for the foreseeable future. We do not have any existing credit facilities under which we could borrow funds. We may seek to raise additional funds through various sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This is particularly true if we experience additional adverse events, if our clinical data is not positive, or economic and market conditions deteriorate. Although we previously have been successful in obtaining financing through our equity securities offerings, there can be no assurance that we will be able to do so in the future. To the extent we raise additional capital through the sale of equity or ~~convertible~~ debt securities, the ownership interests of our shareholders will be diluted. Debt financing, if available, may involve agreements that include conversion discounts or covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third- party funding, marketing and distribution arrangements or other collaborations or strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. It is possible that financing will not be available or, if available, may not be on favorable terms. The availability of financing could be affected by many factors, including, among others: ● the results of our clinical trials and other scientific and clinical research; ● our ability to obtain regulatory approvals; ● market acceptance of DM199 or any future product candidates; ● the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies; ● various events outside our control, including without limitation geopolitical events **and** ~~, such as the~~ current ~~war~~ **wars** ~~between Russia and Ukraine and the conflict between Israel and Hamas~~; ● the status of strategic alliance agreements; and ● other relevant commercial considerations. If adequate funding is not available, we may be required to implement cost reduction strategies; delay, reduce or eliminate one or more of our product development programs; relinquish significant rights to DM199 or future product candidates ~~or~~ **;** obtain funds on less favorable terms than we would otherwise accept; and / or divest assets or cease operations through a merger, sale or liquidation of our Company **. We have incurred substantial losses since our inception and expect to continue to incur substantial losses for at least three or four years and may never achieve or sustain profitability** . We are a clinical stage biopharmaceutical company focused on the development of our DM199 product candidate. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront financial expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. ~~Additionally, there has been a general decline in the biotech sector since February 2021, which has further increased the risks associated with investment in biopharmaceutical product development.~~ We do not have any products approved by regulatory authorities and have not generated any revenues from product sales to date, and do not expect to generate any revenue from the sale of products for at least three or four years. We have incurred significant R & D and ~~other administrative~~ **G & A** expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we ~~have not been profitable and~~ have incurred significant operating losses in every reporting period since our inception **and we may never achieve or sustain profitability** . For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , we incurred a net loss of $ ~~19~~ **24** . 4 million and $ ~~13~~ **19** . ~~7~~ **4** million, respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~115~~ **140** . ~~6~~ **0** million. 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. We expect to continue to incur substantial operating losses as we continue our R & D activities, planned clinical trials, including our Phase 2 / 3 ReMEDy2 trial **and the PE trial** , regulatory activities and other administrative expenses and to support the development of DM199 or any future product candidate to a point where it can be out- licensed or receives required regulatory approvals and may be commercially sold and we begin to recognize future product sales, or receive royalty payments, licensing fees and / or milestone payments sufficient to generate revenues to fund our continuing operations. We expect our operating losses to increase in the near term as we continue development of DM199 and the clinical trials required to seek regulatory approval for DM199, or any future product candidate. We are unable to predict the extent of any future losses or when we will become profitable, if ever. Our failure to ~~become~~ **achieve** and ~~remain~~ **sustain** ~~profitable~~ **profitability** may depress the market price of our common shares and could impair our ability to raise capital, continue to develop DM199, or any future product candidate, expand our business and product offerings or continue our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis ~~. Potential future disruptions in access to bank deposits or lending commitments due to bank failure, could materially and adversely affect our liquidity, our business, financial condition and stock price. The early 2023 closures of Silicon Valley Bank, Signature Bank and First Republic Bank and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC) created bank- specific and broader financial institution liquidity risk and concerns. Although the depositors at these financial institutions have continued to have access to their funds, even those in excess of the standard FDIC insurance limits, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages. Although we did not have deposits at Silicon Valley Bank, Signature Bank or First Republic Bank, the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and / or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we~~

~~may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. In addition, the ability of our suppliers, vendors, and others in which we do business to access their cash and cash equivalents and investments or to obtain any necessary financing to continue their respective businesses could be threatened, which in turn, could harm our business~~ . The regulatory approval process is expensive, time- consuming and uncertain and may prevent us or any future partner or collaborator from obtaining approvals for the commercialization of DM199 or any future product candidate. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Our DM199 or any future product candidate, and the activities associated with their development and commercialization, including design, research, testing, manufacture, quality control, recordkeeping, labeling, packaging, storage, advertising, promotion, sale, distribution, import, export and reporting of safety and other post- market information, are subject to comprehensive regulation by the FDA, the EMA and other similar foreign regulatory agencies. Failure to obtain marketing approval for DM199 or any future product candidate will prevent us or any future partner or collaborator from commercializing the product candidate. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on a future partner, collaborator or third- parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, EMA or other regulatory authorities may determine that DM199 or any future product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit its commercial use. One issue of which we are aware is that because the plastic bags we use in the IV administration of DM199 are made of PVC, certain countries have banned or limited the use of PVC in a manner that may limit our ability to conduct the ~~trails~~ **trials** in such countries, or in the future in the event we are able to obtain required regulatory approvals, may limit the salability of DM199 in certain countries, thereby decreasing our worldwide market opportunity. Additionally, the regulatory approval process and requirements can change substantially based on amendments to federal regulations, new or amended FDA guidance documents governing the regulatory approval process, and even changes in FDA approval priorities based on the government administration as was recently seen in response to the COVID- 19 pandemic. As a result, any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. Our or any future partner' s inability to obtain regulatory approval for DM199 or any future product candidate, or if such approval is limited, could substantially harm our business. The FDA and other federal and state agencies, including the U. S. Department of Justice (DOJ), closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products. The FDA and DOJ impose ~~stringent~~ restrictions on manufacturers' communications regarding off- label use,, sales and marketing activities, transparency laws, and reimbursement obligations, which restrictions can change substantially based on new and / or amended government interpretations of regulatory priorities, new and / or amended federal regulations, and other external forces. If we do not market our products for ~~their~~ approved indications, we may be subject to enforcement action for off- label marketing. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the **federal** False Claims Act, the **federal** Anti- Kickback Statute, the Sunshine Act and other federal and state health care fraud and abuse laws, as well as state consumer protection laws. Our or any future partner' s failure to comply with all regulatory requirements, or the later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including: ● litigation involving patients using our products; ● restrictions on such products, manufacturers or manufacturing processes; ● restrictions on the labeling or marketing of a product; ● restrictions on product distribution or use; ● requirements to conduct post- marketing studies or clinical trials; ● warning or untitled letters; ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● damage to relationships with any then current or potential partners; ● unfavorable press coverage and damage to our or any future partner' s reputation; ● refusal to permit the import or export of our products; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. Non- compliance by us or any future partner or collaborator with regulatory requirements regarding ongoing safety monitoring, or pharmacovigilance, and with requirements related to the development of products, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to ~~significant~~ penalties and sanctions. We may be unable to obtain FDA acceptance of INDs to commence future clinical trials in the United States or on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner. Prior to commencing additional clinical trials in the United States for DM199 or any future product candidate, we will be required to have an accepted IND for each product candidate and for each targeted indication. In April 2021, we filed, and in May 2021, the FDA accepted, an IND for the Phase 2 / 3 ReMEDy2 trial in patients with AIS. However, in July 2022, the FDA imposed a clinical hold on the IND under which we are conducting our Phase 2 / 3 ReMEDy2 trial, which clinical hold was subsequently lifted in June 2023 **. If the Phase 2 IST study of DM199 in PE is successful, we plan to file an IND to enable us to commence additional clinical trials studying DM199 for the treatment of PE. There is no assurance that this IND will be filed on a timely basis or accepted by the FDA on a timely basis or at all** . A submission of an IND may not

necessarily result in the FDA allowing further clinical trials to begin and, once begun, issues, such as clinical holds, may arise that will require us to suspend or terminate such clinical trials. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the future. Failure to obtain acceptance of any future INDs may cause the development of DM199 or any future product candidate to be delayed or terminated, which could materially and adversely affect our business and prospects. We have received Fast Track designation for DM199 for the treatment of AIS, and we may seek such designation for other uses of DM199 or future product candidates. Fast Track designation may not lead to faster development or a faster FDA review or approval process, and it does not increase the likelihood that DM199 will receive marketing approval in the United States. Further, there is no guarantee we will be able to maintain such designation. In September 2021, we received Fast Track designation from the FDA for DM199 for the treatment of AIS where tPA and / or mechanical thrombectomy are not indicated or medically appropriate. The FDA may grant Fast Track designation to a drug that is intended to treat a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need. The FDA provides opportunities for more frequent interactions with the review team for a Fast Track product, including pre- IND meetings, end- of- phase 1 meetings and end- of- phase 2 meetings with the FDA to discuss study design, extent of safety data required to support approval, dose- response concerns and use of biomarkers. A Fast Track product may also be eligible for rolling review, where the FDA reviews portions of a marketing application before the sponsor submits the complete application. However, Fast Track designation for DM199 may not result in a faster development process or a faster review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. Any delay in the review process or in the approval of DM199 will delay revenue from potential sales and will increase the capital necessary to fund our development programs and operations. In addition, the FDA may rescind the Fast Track designation for DM199 if the FDA later determines that DM199 no longer meets the qualifying criteria for Fast Track designation. Current and future legislation may increase the difficulty and cost for us and any future partner or collaborator to obtain marketing approval of and commercialize DM199 or any future product candidate and affect the prices we may obtain. In the United States and many foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and data privacy that could prevent or delay marketing approval of DM199 or any future product candidate, restrict or regulate post- approval activities and affect our ability to profitably sell DM199 or any future product candidate for which we obtain marketing approval. **Further, changes in government administrations may result in changed administrative or legislative priorities and could also prevent or delay marketing approval of DM199 or any future product candidate, restrict or regulate post- approval activities and affect our ability to profitably sell DM199 or any future product candidate for which we obtain marketing approval.** Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. For example, the Affordable Care Act (~~"~~ACA ~~"~~) enacted in the United States in 2010, and principally taking effect in 2014, included measures to change health care delivery, decrease the number of individuals without insurance, ensure access to certain basic health care services and contain the rising cost of care. This healthcare reform movement, including the enactment of the ACA, has significantly changed health care financing by both governmental and private insurers in the United States. With respect to pharmaceutical manufacturers, the ACA increased the number of individuals with access to health care coverage, including prescription drug coverage, but it simultaneously imposed, among other things, increased liability for rebates and discounts owed to certain entities and government health care programs, fees for the manufacture or importation of certain branded drugs and transparency reporting requirements under the Physician Payments Sunshine Act. In addition to the ACA, other federal health reform measures have been proposed and adopted in the United States. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we may receive for any product, if approved. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The U. S. federal government has **recently** prioritized and **may** ~~will likely~~ continue to prioritize policies targeting reducing drug prices and healthcare spending and ~~are~~ **may remain** committed to lowering spending in federal government programs. The Inflation Reduction Act of 2022, which was signed into law on August 16, 2022, includes provisions aimed at lowering prescription drug costs for Medicare patients and reducing the federal government' s spending on prescription drugs by requiring certain prescription drug prices to be negotiated directly with the government, certain rebates to be paid by prescription drug companies, and certain spending caps to be implemented, among other measures. The implementation of cost containment measures or other healthcare reforms may prevent us or a future partner **or collaborator** from being able to generate sufficient revenue, attain profitability or even commercialize at all DM199 or any future product candidate. **Policies implemented by the U. S. federal government may also introduce new, unexpected challenges such as supply chain disruptions based on international tariffs or taxation, other inflation- related measures and other measures that may affect the revenue, profitability and / or commercialization of DM199.** Future legislation in the United States, Europe or other countries, and / or regulations and policies adopted by the FDA, the EMA or comparable regulatory authorities, may increase the time and cost required for us or any future partners or collaborators to conduct and complete clinical trials of our current or any future product candidates. The FDA and the ~~European Medicines Agency (~~EMA ~~)~~ have each established regulations to govern the ~~drug~~ **therapeutic** product development and approval process, as have other foreign regulatory authorities. The policies of the FDA, the EMA and other regulatory authorities may change. For example, in December 2016, the 21st Century Cures Act (Cures Act) was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but not all of its provisions have yet been implemented. Additionally, the EMA issued Annex 1: the Manufacture of Sterile Medicinal Products which was effective August 15, 2023, intended to update standards to reflect change in regulatory and manufacturing environments and to remove ambiguity and inconsistencies in regulations

governing the manufacture of sterile medicinal products. ~~.~~ We cannot predict what if any effect the Cures Act, Annex 1 or any existing or future guidance from the FDA, EMA or other regulatory authorities will have on the development of DM199 or any future product candidate. We rely and will continue to rely on third parties to support the planning, execution and / or monitoring of our preclinical and clinical trials, and their failure to perform as required could cause delays in completing our product development and substantial harm to our business. We rely and will continue to rely on third parties to conduct a significant portion of our preclinical and clinical development activities. Preclinical activities include in **vitro and in** vivo studies in specific disease models, pharmacology and toxicology studies and assay development. Clinical development activities include trial design, regulatory submissions, clinical site and patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in our relationship with third parties, or if they are unable to provide quality services in a timely manner and at a feasible cost, including as a result of staffing disruptions, our development programs may face delays. Further, if any of these third parties fail to perform as we expect or if their work fails to meet regulatory requirements, our clinical testing could be delayed, cancelled or rendered ineffective. ~~This happened~~ **For example, our prior contract research organization that we engaged** to ~~us in~~ **assist with our ReMEDy2 trial did not perform as we anticipated, thereby adversely affecting** the ~~past~~ **conduct of the trial** and ~~resulted~~ **resulting** in ~~us commencing~~ **delays in site activation and enrollment. No assurance can be provided that will not have similar issues with CROs that we have engaged to assist with the trial in non- U. S. jurisdictions. In addition, in connection with a prior clinical trial, we commenced** litigation against Pharmaceutical Research Associates Group B. V., which was acquired by ICON plc ~~in July 2021~~ (PRA Netherlands), as a result of its handling of a double- blinded, placebo- controlled, single- dose and multiple- dose study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and proof of concept of DM199 in healthy subjects and in patients with Type 2 diabetes mellitus, as described later in this report ~~; and could happen again~~ . We rely on contract manufacturers over whom we have limited control. If we are subject to quality, cost or delivery issues with the materials supplied by these or future contract manufacturers, we may be unable to produce adequate supplies of DM199 or any future product candidate, and our clinical and business operations could suffer significant harm. Completion of our clinical trials and commercialization of our DM199 product candidate and any future product candidate require access to, or development of, facilities to manufacture our product candidates at sufficient yields and, ultimately, assuming approval, at commercial scale. Clinical and commercial drug product must be produced under applicable ~~cGMP~~ **GMP** regulations. Failure of our **contract development and manufacturing organizations (** ~~CMOs~~ **CDMOs)** to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We rely on ~~CMOs~~ **CDMOs** for manufacturing, filling, labeling, packaging, storing and shipping DM199 in compliance with applicable cGMP regulations. The FDA and other regulatory agencies ensure the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. As a ~~company~~ **Company** , we have ~~no~~ **limited** direct experience in manufacturing or managing third parties in manufacturing our DM199 product candidate in the volumes that are expected to be necessary to support commercialization, if DM199 is approved. Our efforts to establish these capabilities may not meet our requirements as to scale- up, timeliness, yield, cost or quality in compliance with applicable ~~cGMP~~ **GMP** regulations. We or any future partner or collaborator or our ~~CMOs~~ **CDMOs** may encounter difficulties in production, which may include the following, among others: ● costs and challenges associated with scale- up and attaining sufficient manufacturing yields; ● supply chain issues, including the timely availability and shelf life requirements of raw materials and supplies and the lack of redundant and backup suppliers; ● quality control and assurance; ● shortages of qualified personnel and capital required to manufacture large quantities of our product candidate; ● competing capacity needs at ~~CMOs~~ **CDMOs** supporting product development as quantities for supply increase; ● establishment of commercial supply capacity through binding supply agreements or to do so on acceptable terms; ● compliance with regulatory requirements that vary in each country where a product might be sold; ● capacity limitations and scheduling availability in contracted facilities; and ● natural disasters, cyberattacks, which could subject us to an increased regulatory burden and increased costs of compliance, or other force majeure events that affect CDMO facilities and possibly limit production or cause loss of product inventory. We do not have long- term supply agreements with any of our ~~CMOs~~ **CDMOs** and we purchase our required supply on an order- by- order basis. There can be no assurances that our current ~~CMOs~~ **CDMOs** or any future ~~CMOs~~ **CDMOs** will be able to meet our timetable and requirements for our DM199 product candidate or any future product candidate. If we are unable to arrange for alternative third- party manufacturing sources on commercially reasonable terms or in a timely manner, we may be delayed in the development of DM199 or any future product candidate. Our dependence upon our current ~~CMOs~~ **CDMOs** and any future ~~CMOs~~ **CDMOs** for the manufacture of our product candidates may adversely affect our ability to develop our product candidates in a timely and competitive basis and, if we or a future partner are able to commercialize our product candidates, may adversely affect our revenues from product sales and significantly harm our business. Future development collaborations are expected to be important to us. If we are unable to enter into or maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected. **We** ~~In the future, we~~ intend ~~to seek~~ to collaborate with pharmaceutical ~~and~~ **,** biotechnology **and other** companies **and organizations** for the **future** development **, funding** and / or commercialization of DM199. We face significant competition in seeking appropriate collaborators or partners. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator' s or partner' s resources and expertise, the terms and conditions of the proposed collaboration **,** and the proposed collaborator' s or partner' s evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators or partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of and / or seek alternative means to commercialize our DM199 product candidate resulting in, among other things, reducing or delaying our development program, delaying our potential development schedule **,** or reducing the scope of research activities. If we fail to enter into one or more collaborations and do not have sufficient funds or expertise to undertake the necessary development or commercialization activities, we may not be able to continue or further

develop DM199 and our business may be materially and adversely affected. Future collaborations we may enter into may involve significant risks, including, among others: ● collaborators may have significant discretion in determining the efforts and resources that they will apply to the collaboration; ● collaborators may not perform their obligations as expected; ● changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities; ● collaborators may **insist upon our relinquishment of certain rights with respect to our product candidates; ● collaborators may** delay nonclinical or clinical development, provide insufficient funding for product development of targets selected by us, stop or abandon nonclinical or clinical development for a product candidate, or repeat or conduct new nonclinical and clinical development for a product candidate; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products; ● product candidates discovered in collaboration with us may be viewed by our future collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates; ● disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the preclinical or clinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; ● collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and ● collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the way we are perceived in the business and financial communities could be adversely affected. If our collaborations do not result in the successful development of DM199, or any future product candidate, development could be delayed, and we may need additional resources to develop DM199 or any future product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our future collaborators. Our inability to maintain contractual relationships with physicians could have a negative impact on our research and development. We maintain contractual relationships with respected physicians in hospitals and universities who assist us in the design **and conduct** of our clinical trials and interpretation of trial results. If we are unable to enter into and maintain these relationships, our ability to develop, obtain required regulatory approvals for, and market our DM199 or any future product candidate could be adversely affected. In addition, it is possible that U. S. federal and state and international laws requiring us to disclose payments or other transfers of value, such as gifts or meals, to surgeons and other healthcare providers could have a chilling effect on the relationships with individuals or entities that may, among other things, want to avoid public scrutiny of their financial relationships with us. We are a party to a license agreement relating to an expression system and cell line for use in the production of DM199 and DM300. We may need to obtain additional licenses from others to advance our R & D activities or allow the commercialization of DM199 or any other product candidates we may identify and pursue. Future license agreements may impose various development, diligence, commercialization and other obligations on us. If any of our current or future in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain access to technologies that are material to our business, and we may be required to cease our development and commercialization of DM199 or other product candidates that we may identify or to seek alternative manufacturing methods. However, suitable alternatives may not be available or the development of suitable alternatives may result in a significant delay in our commercialization of DM199. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including, among others: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which, our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patent and other rights under our collaborative development relationships; ● our diligence obligations under the license agreement and what activities satisfy those diligence obligations; ● the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and ● the priority of invention of patented technology. In addition, the agreements under which we currently license intellectual property or technology from a third party are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology ~~,~~ or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have in- licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be unable to adequately protect our technology and enforce our intellectual property rights and our competitors may take advantage of our development efforts or acquired technology and compromise our prospects for marketing and selling DM199 or any future product candidate. We believe that patents and other proprietary rights are key to our business. Our policy is to file patent applications to protect technology, inventions and improvements that may be important to the development of DM199 or any future product candidate. We also rely upon trade secrets, know- how and continuing technological innovations to develop and maintain our competitive position.

We plan to enforce our issued patents and our rights to proprietary information and technology. We review third- party patents and patent applications, both to refine our own patent strategy and to monitor the landscape related to our technology. Our success depends, in part, on our ability to secure and protect our intellectual property rights and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by us. We have a number of patents, patent applications and rights to patents related to our compounds, product candidates and technology, but we cannot be certain that they will be enforceable or provide adequate protection or that pending patent applications will result in issued patents. To the extent that development, manufacturing and testing of our product candidates is performed by third party contractors, such work is performed pursuant to fee for service contracts. Under the contracts, all intellectual property, technology know- how and trade secrets related to our product candidate arising under such agreements are our exclusive property and must be kept confidential by the contractors. It is not possible for us to be certain that we have obtained from the contractors all necessary rights to such technologies. Disputes may arise as to the scope of the contract or possible breach of contract. No assurance can be given that our contracts will be enforceable or would be upheld by a court. The patent positions of pharmaceutical and biotechnology firms, ~~ourselves~~ **us** included, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved. Therefore, it is not clear whether our pending patent applications will result in the issuance of patents with commercially meaningful protections or at all, or whether we will develop additional proprietary products which are patentable. Part of our strategy is based on our ability to secure a patent position to protect our technology. There is no assurance that we will be successful in this approach and failure to secure adequate patent protection may have a material adverse effect upon us and our financial condition. Also, we may fail in our attempt to commercialize products using currently patented or licensed technology without having to license additional patents. Moreover, it is not clear whether the patents issued or to be issued will provide us with any competitive advantages or if any such patents will be the target of challenges by third parties, whether the patents of others will interfere with our ability to market our products, or whether third parties will circumvent our patents by means of alternate processes. Furthermore, it is possible for others to develop products that have the same effect as our product candidates or technologies on an independent basis or to design around technologies patented by us. Patent applications relating to or affecting our business may have been filed by pharmaceutical or biotechnology companies or academic institutions. Such applications may conflict with our technologies or patent applications and such conflict could reduce the scope of patent protection that we could otherwise obtain or even lead to the rejection of our patent applications. There is no assurance that we can enter into licensing arrangements on commercially reasonable terms or develop or obtain alternative technology in respect of patents issued to third parties that incidentally cover our products or production technologies. Any inability to secure licenses or alternative technology could result in delays in the introduction of some of our product candidates or even lead to us being prevented from pursuing the development, manufacture or sale of certain products. Moreover, we could potentially incur substantial legal costs in defending legal actions that allege patent infringement, or by initiating patent infringement suits against others. It is not possible for us to be certain that we are the creator of inventions covered by pending patent applications or that we were the first to invent or file patent applications for any such inventions. While we have used commercially reasonable efforts to obtain assignments of intellectual property from all individuals who may have created materials on our behalf (including with respect to inventions covered by our patents and pending patent applications), it is not possible for us to be certain that we have obtained all necessary rights to such materials. No assurance can be given that our patents, or patent applications if issued, would be upheld by a court, or that a competitor' s technology or product would be found to infringe on our patents. Moreover, much of our technology know- how that is not patentable may constitute trade secrets. Therefore, we require our employees, consultants, advisors and collaborators to enter into confidentiality agreements either as stand- alone agreements or as part of their employment or consulting contracts. However, no assurance can be given that such agreements will provide meaningful protection of our trade secrets, know- how or other proprietary information in the event of any unauthorized use or disclosure of confidential information. Also, while we have used commercially reasonable efforts to obtain executed copies of such agreements from all employees, consultants, advisors and collaborators, no assurance can be given that executed copies of all such agreements have been obtained. A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third- party patent rights cover our product candidates, we or any future collaborator, would be required to seek licenses from the holders of these patents in order to manufacture, use or sell our product candidates, and payments under them would reduce profits from our product candidates. We are currently unable to predict the extent to which we may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights, and whether a license to such patents will be available on acceptable terms, or at all. There may be patents in the United States or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder or eliminate our ability to develop, manufacture and market our product candidates and have a material adverse effect on our business, financial condition, results of operations, and prospects. Changes in patent law and its interpretation could diminish the value of our patents in general, thereby impairing our ability to protect DM199 or any future product candidate. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently uncertain. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or any licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U. S. Congress, the federal courts, the U. S. Patent and Trademark Office (USPTO) and the European Patent Office (EPO), the laws and regulations governing patents could change in unpredictable ways that would weaken our or any licensors' or collaborators' ability to obtain new patents or to enforce existing

patents and patents we or any licensors or collaborators may obtain in the future. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act (the America Invents Act), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but 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 such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or any licensor 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 or any licensor' s patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent in USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in- licensed patent applications and the enforcement or defense of our owned or in- licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Third parties may claim that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights or otherwise to protect our proprietary information and to prevent its disclosure, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is in our favor. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability (including treble damages and attorneys' fees if we are found to have willfully infringed) and require us or any third- party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be available on commercially acceptable terms or at all. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Competitors may infringe **on** our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Moreover, similar challenges may be made by third parties outside the context of litigation, e. g., via administrative proceedings such as post grant or inter partes review in the United States or via oppositions or other similar proceedings in other countries / regions. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation, validity or enforceability, interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation or such other proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. 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 material adverse effect on the market price of our common shares. Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them. Because we rely on third parties to develop and manufacture our DM199 product candidate, we may share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, employment or consulting agreements or other similar agreements with our collaborators, advisors,

employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees, and consultants to publish data potentially relating to our trade secrets. In the future, we may also conduct joint R & D programs which may require us to share trade secrets under the terms of R & D collaboration or similar agreements. We cannot be certain that our current or any future agreements have been or will be entered into with all relevant parties. Moreover, despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. A competitor' s discovery of our trade secrets may impair our competitive position and could have a material adverse effect on our business, financial condition, results of operations, and prospects. Patent terms may be inadequate to protect the competitive position of DM199 or any future product candidate for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Certain extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. 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. As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and 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 non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against

government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. We **rely heavily on the capabilities and experience of our key executives and clinical personnel and advisors; and the loss of any of them could affect our ability to develop DM199 or any future product candidate. We** depend heavily on members of our management team and certain other key personnel, including in particular our clinical personnel. We also depend on our clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial, medical, clinical and regulatory personnel, particularly as we continue to expand our activities and seek regulatory approvals for clinical trials and eventually our DM199 product candidate. We enter into agreements with scientific and clinical collaborators and advisors, key opinion leaders **,** and academic partners in the ordinary course of our business. We also enter into agreements with physicians and institutions that will recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for these types of personnel from other companies, research and academic institutions ~~, government entities~~ and other organizations. We cannot predict our success in hiring or retaining the personnel we require for our continued growth. The loss of the services of any of our key executive officers ~~,~~ **and** clinical personnel and advisors could potentially harm our business, operating results or financial condition. As we advance our DM199 product candidate through clinical trials **and** ~~, or~~ develop ~~any~~ future product candidates, we **have expanded** ~~expect to increase~~ our product development, scientific, clinical, regulatory and compliance **,** and administrative headcount ~~to manage these programs~~. **As** ~~In furtherance~~ of ~~these efforts~~ **December 31** , **2024,** we ~~recently hired a new Chief Medical Officer and hired a Chief Business Officer during~~ **had 28 full time employees, compared to 18 full time employees, as of December 31,** 2023. In addition, to continue to meet our obligations as a U. S. public reporting company, we will likely need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we: ● successfully attract and recruit new employees with the expertise and experience we ~~will~~ require; ● manage our clinical programs effectively, which have been and will continue to be conducted at numerous clinical sites; ● develop a marketing, distribution and sales infrastructure if we seek to market our products directly; and ● continue to improve our operational, manufacturing, quality assurance, financial and management controls, reporting systems and procedures. If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected. Even if DM199 or any future product candidate is successfully developed and receives regulatory approval, it may not gain market acceptance among physicians, patients, ~~healthcare~~ **third- party** payers, such as private insurers or governments and other funding parties. The degree of market acceptance for DM199 or any product candidate we develop will depend on a number of factors including, among others: ● demonstration of sufficient clinical efficacy and safety; ● the prevalence and severity of any adverse side effects; ● limitations or warnings contained in the product' s approved labeling; ● cost- effectiveness and availability of acceptable pricing; ● the availability of alternative treatment methods and the superiority of alternative treatment methods; ● the effectiveness of marketing and distribution methods and support for the product; and ● coverage and reimbursement policies of government and third- party payers to the extent that the product could receive regulatory approval but not be approved for coverage by or receive adequate reimbursement from government and quasi- government agencies or other third- party payers. Our or any future partner' s ability to successfully commercialize DM199 or any future product candidate will depend, in part, on the extent to which coverage of and adequate reimbursement for such product and related treatments will be available from governmental health payer programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. No assurance can be given that third- party coverage or adequate reimbursement will be available that will allow us or any future partner to obtain or maintain price levels sufficient for the realization of an appropriate return on our investment in product development. Coverage and adequate reimbursement are critical to new product acceptance by healthcare providers. There is no uniform coverage and reimbursement policy among third- party payers in the United States; however, private third- party payers may follow Medicare coverage and reimbursement policy in setting their own coverage policy and reimbursement rates. Additionally, coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are or subsequently become available. Even if coverage is obtained for DM199 or any future product candidate, the related reimbursement rates might not be adequate to make the product attractive to providers, or may require patient cost sharing (e. g., copayments and / or deductibles) that patients find unacceptably high. In addition, healthcare reform and controls on healthcare spending may limit coverage of the product and the price we charge and get paid for the product and the volumes thereof that we can sell. Patients are unlikely to use DM199 or any future product candidate unless coverage is provided and reimbursement is adequate to cover a significant portion of its cost. Outside of the United States, the successful commercialization of DM199 or any future product candidate will depend largely on obtaining and maintaining government coverage, because in many countries, patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our or a future partner' s ability to sell DM199 or any future product candidate on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue- related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. We or any future partner will likely face competition from other biotechnology and pharmaceutical companies, many of which have substantially greater resources, and our DM199 product candidate may face competition sooner than expected and our financial condition and operations will

suffer if we fail to compete effectively. Technological competition is intense in the industry in which we operate. Development of new, potentially competitive therapies comes from pharmaceutical companies, biotechnology companies and universities, as well as companies that offer non- pharmaceutical solutions. Many of our competitors have substantially greater financial and technical resources; more extensive R & D capabilities; and greater marketing, distribution, production and human resources than we do. Moreover, competitors may develop products more quickly than us and may obtain regulatory approval for such products more rapidly than we do. Products and processes which are more effective than those that we intend to develop may be developed by our competitors. R & D by others may render our product candidates non- competitive or obsolete. We believe that DM199 could qualify for 12 years of data exclusivity in the United States under the Biologics Price Competition and Innovation Act of 2009 ~~(BPCIA)~~ , which was enacted as part of the ACA. Under the BPCIA, an application for a biosimilar product, or BLA, cannot be submitted to the FDA until four years, or if approved by the FDA, until 12 years, after the original brand product identified as the reference product is approved under a BLA. The BPCIA provides an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an existing brand product. This law is complex and is only beginning to be interpreted and implemented by the FDA. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for DM199 or any future product candidate that is a biologic. There is also a risk that the U. S. Congress could repeal or amend the BPCIA to shorten this exclusivity period, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Even if, as we expect, our DM199 product candidate is considered to be a reference product eligible for 12 years of exclusivity under the BPCIA, another company could market competing products if the FDA approves a full BLA for such product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the BPCIA could result in a shorter exclusivity period for our DM199 product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our **estimates of the market opportunity for our DM199 product candidate for the treatment of AIS, PE and any other indications we choose to pursue or any other product candidates we develop are based on a number of assumptions and may prove to be inaccurate. The actual market may be smaller than we believe, which would adversely affect our business, prospects, operating results and financial condition. Our ReMEDy2 trial excludes patients who are eligible to receive mechanical thrombectomy, specifically participants with large vessel occlusions in the intracranial carotid artery or the M1 segment of the middle cerebral, vertebral or basilary arteries or those that are otherwise eligible for MT. As a result of our recent protocol amendment for the ReMEDy2 trial, participants treated with tPA or TNK, (thrombolytic agents) intended to dissolve blood clots, are now eligible for participation if they continue to experience a persistent neurological deficit after receiving thrombolytic treatment and meet all other trial criteria, including repeat brain imaging to assess any hemorrhagic (bleeding) transformation. We believe the ReMEDy2 trial population is representative of the approximately 80 % of AIS patients who do not have treatment options today, primarily due to the limitations on treatment with tPA / TNK and / or MT. We estimate total addressable markets for our DM199 product candidate for the treatment of AIS, PE and any other indications we choose to pursue or any other product candidates we develop. Our estimates and forecasts are based on a number of complex assumptions, internal and third- party estimates in published literature, and other business data, including assumptions and estimates relating to our ability to manage operating expenses of, invest in, and develop and generate revenue from DM199 or any other product candidates we develop in the future. While we believe our assumptions and the data underlying our estimates and key performance indicators are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and metrics. Consequently, our estimates of the total addressable markets and our forecasts of market growth may prove to be incorrect. For example, if the annual total addressable markets or the potential market growth is smaller than we have estimated or if the key business metrics we utilize to forecast commercial opportunities are inaccurate, it may have an adverse effect on our business, prospects, operating results and financial condition. Our** common shares trade on The Nasdaq Capital Market under the trading symbol " DMAC. " During ~~2023~~ **2024** , the sale price of our common shares ranged from $ ~~1~~ **2** . ~~27~~ **14** to $ ~~4~~ **6** . ~~75~~ **41** per share. A number of factors could influence the volatility in the trading price of our common shares, including changes in the economy ~~or~~ **and** in the financial markets, industry related developments **in the overall biotech and pharmaceutical sectors, and the impact of material events and changes in our operations** , such as ~~a general decline in the biotech sector, and the impact of material events and changes in~~ our **progress in** ~~operations, such as~~ our clinical **trials,** results **thereof** ~~including the prior clinical hold on the IND for our ReMEDy2 trial~~ , operating results and financial condition. Each of these factors could lead to increased volatility in the market price of our common shares. In addition, the market prices of the securities of our competitors may also lead to fluctuations in the trading price of our common shares. During ~~2023~~ **2024** , the daily trading volume of our common shares ranged from ~~4~~ **approximately 5** , ~~700~~ **200** shares to ~~905~~ **1** , ~~600~~ **179, 000** shares. Although we anticipate a more active trading market for our common shares in the future, we can give no assurance that a more active trading market will develop or be sustained. If we do not have an active trading market for our common shares, it may be difficult for you to sell our common shares at a favorable price or at all. **We may issue additional common shares resulting in share ownership dilution.** Future dilution will likely occur due to anticipated future equity issuances by us. To the extent we raise additional capital through the

sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted. In addition, as of December 31, ~~2023~~ **2024**, we had outstanding options to purchase ~~3~~ **4**, ~~423~~ **277**, ~~103~~ **028** common shares, deferred stock units representing ~~196~~ **267**, ~~572~~ **553** common shares and ~~927~~ **2**, ~~215~~ **899, 149** common shares reserved for future issuance in connection with future grants under the DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan and the DiaMedica Therapeutics Inc. 2021 Employment Inducement Incentive Plan and options to purchase ~~447~~ **415**, ~~910~~ **410** common shares and deferred stock units representing 17, 333 common shares under our prior equity compensation ~~plan~~ **plans**. If these or any future outstanding options or deferred stock units are exercised or otherwise converted into our common shares, our shareholders will experience additional dilution **. If there are substantial sales of our common shares or the perception that such sales may occur, the market price of our common shares could decline**. Sales of substantial numbers of our common shares, or the perception that such sales may occur, could cause a decline in the market price of our common shares. Any sales by existing shareholders or holders who exercise their warrants or stock options may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common shares. We are a " smaller reporting company, " and because we have opted to use the reduced disclosure requirements available to us, certain investors may find investing in our common shares less attractive. We are currently a " smaller reporting company " under the **U. S.** federal securities laws and, as such, are subject to scaled disclosure requirements afforded to such companies. For example, as a smaller reporting company, we are subject to reduced executive compensation disclosure requirements. Our shareholders and investors may find our common shares less attractive as a result of our status as a " smaller reporting company " and our reliance on the reduced disclosure requirements afforded to these companies. If some of our shareholders or investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the market price of our common shares may be more volatile. We are a British Columbia corporation. Our corporate affairs and the rights of holders of our common shares are governed by British Columbia' s Business Corporations Act (BCBCA) and applicable securities laws, which laws may differ from those governing a company formed under the laws of a United States jurisdiction. The provisions under the BCBCA and other relevant laws may affect the rights of shareholders differently than those of a company governed by the laws of a United States jurisdiction and may, together with our Notice of Articles and Articles, have the effect of delaying, deferring or discouraging another party from acquiring control of our Company by means of a tender offer, proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and the Delaware General Corporation Law (DGCL), by way of example, that may be of most interest to shareholders include the following: ● for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our Notice of Articles), the BCBCA, subject to the provisions of our Articles, generally requires two- thirds majority vote by shareholders; whereas, the DGCL generally only requires a majority vote of shareholders; ● under the BCBCA, a holder of 5 % or more of our common shares can requisition a special 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; ● our Articles require two- thirds majority vote by shareholders to pass a resolution for one or more directors to be removed; whereas the DGCL only requires the affirmative vote of a majority of the shareholders; and ● our Articles may be amended by resolution of our directors to alter our authorized share structure, including to (a) subdivide or consolidate any of our shares and (b) create additional classes or series of shares; whereas, under the 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 alternations to a corporation' s authorized share structure. We cannot predict if investors 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. We were classified as a " passive foreign investment company " in **2024, 2023,** 2022 and ~~2023~~ **certain prior years** and may continue to be **so classified** in future taxable years, which may have adverse U. S. federal income tax consequences for U. S. shareholders and adversely affect the level of interest in our common shares by U. S. investors. General Rule. For any taxable year in which 75 % or more of our gross income is passive income, or at least 50 % of the value of our assets (where the value of our total assets is determined based upon the market value of our common shares at the end of each quarter or other measuring period) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company (PFIC) for U. S. federal income tax purposes. The percentage of a corporation' s assets that produce or are held for the production of passive income generally is determined based upon the average ratio of passive assets to total assets calculated at the end of each measuring period. Calculation of the value of assets at the end of each measuring period is generally made at the end of each of the four quarters that make up the company' s taxable year, unless an election is made to use an alternative measuring period (such as a week or month). The " weighted average " of those periodic values is then used to determine the value of assets for the passive asset test for the taxable year. In proposed regulations section 1. 1297- 1 (d) (2), a limited exception to the passive asset test valuation rules is provided for the treatment of working capital in order to take into account the short- term cash needs of operating companies. This new rule provides that an amount of cash held in a non- interest bearing account that is held for the present needs of an active trade or business and is no greater than the amount reasonably expected to cover 90 days of operating expenses incurred in the ordinary course of the trade or business of the foreign corporation (for example, accounts payable for ordinary operating expenses or employee compensation) is not treated as a passive asset. The Treasury Department and the IRS indicated that they continue to study the appropriate treatment of working capital for purposes of the passive asset test. PFIC Status Determination. The tests for determining PFIC status for any taxable year are dependent upon a number of factors, some of which are beyond our control, including the value of our assets, the market price of our common shares, and the amount and type of our gross income. Based on these tests **,** ~~(i)~~ we believe that we were a PFIC for the taxable year ended December 31, 2016 **and again** ~~, (ii) we do not believe that we were a PFIC~~ for ~~any of~~ the taxable years ended December 31, ~~2017 through~~ **2022,** December 31, ~~2021~~ **2023**, and ~~(iii)~~ **December 31, 2024. Based on these tests,** we believe that we were **not** a PFIC for

any of the taxable years ended December 31, ~~2022 and~~ **2017 through** December 31, ~~2023~~ **2021** . Our status as a PFIC is a fact-intensive determination made for each taxable year, and we cannot provide any assurance regarding our PFIC status for the taxable year ending December 31, ~~2024~~ **2025** or for future taxable years. U. S. shareholders who own our common shares for any period during which we are a PFIC (which we believe would currently ~~only~~ be those shareholders that held our common shares in the taxable year ended December 31, 2016 ~~,~~ **or any of the taxable years ended** December 31, 2022 ~~or December 31~~ , 2023 **or 2024**) will be required to file IRS Form 8621 for each tax year during which they hold our common shares, unless, after we are no longer a PFIC, any such shareholder makes the " purging election " discussed below. PFIC Consequences. If we are a PFIC for any year during a non- corporate U. S. shareholder' s holding period of our common shares, and the U. S. shareholder does not make a Qualified Electing Fund election (QEF Election) or a " mark- to- market " election, both as described below, then such non- corporate U. S. shareholder generally will be required to treat any gain realized upon a disposition of our common shares, or any so- called " excess distribution " received on our common shares, as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our common shares would not be available. This income generally would be allocated over a U. S. shareholder' s holding period with respect to our common shares and the amount allocated to prior years will be subject to tax at the highest tax rate in effect for that year and an interest charge would be imposed on the amount of deferred tax on the income allocated to prior taxable years. Pursuant to the specific provisions of the PFIC rules, a taxpayer may realize gain on the disposition of common shares if the securities are disposed of by a holder whose securities are attributed to the U. S. shareholder, if the securities are pledged as security for a loan, transferred by gift or death, or are subject to certain corporate distributions. Additionally, if we are a PFIC, a U. S. shareholder who acquires our common shares from a decedent would be denied normally available step- up in tax basis for our common shares to fair market value at the date of death but instead would have a tax basis equal to the lower of the fair market value of such common shares or the decedent' s tax basis in such common shares. Proposed regulations, that are not yet effective, address domestic partnerships and S corporations that own stock in a PFIC for which a QEF election or " mark- to- market " election could be made. Currently, only the domestic partnership or S corporation (and not the partners or S corporation shareholders) can make these elections. The proposed regulations would reverse the current rule so that only the partners or S corporation shareholders — not the partnership or S corporation — could make the elections. These proposed regulations would only apply to partnership or S corporation shareholders' tax years beginning on or after the date they are issued in final form. QEF Election. A U. S. shareholder may avoid the adverse tax consequences described above by making a timely and effective QEF election. A U. S. shareholder who makes a QEF election generally must report, on a current basis, its share of our ordinary earnings and net capital gains, whether or not we distribute any amounts to our shareholders, and would be required to comply with specified information reporting requirements. Any gain subsequently recognized upon the sale by that U. S. shareholder of ~~the~~ **our** common shares generally would be taxed as capital gain and the denial of the basis step- up at death described above would not apply. The QEF election is available only if the company characterized as a PFIC provides a U. S. shareholder with certain information regarding its earnings and capital gains, as required under applicable U. S. Treasury regulations. We intend to provide all information and documentation that a U. S. shareholder making a QEF election is required to obtain for U. S. federal income tax purposes (e. g., the U. S. shareholder' s pro rata share of ordinary income and net capital gain, and a " PFIC Annual Information Statement " as described in applicable U. S. Treasury regulations). Mark- to- Market Election. As an alternative to a QEF Election, a U. S. shareholder may also mitigate the adverse tax consequences of PFIC status by timely making a " mark- to- market " election. A U. S. shareholder who makes the mark- to- market election generally must include as ordinary income each year the increase in the fair market value of the common shares and deduct from gross income the decrease in the value of such shares during each of its taxable years. Losses would be allowed only to the extent of the net mark-to- market gain accrued under the election. If a mark- to- market election with respect to our common shares is in effect on the date of a U. S. shareholder' s death, the tax basis of the common shares in the hands of a U. S. shareholder who acquired them from a decedent will be the lesser of the decedent' s tax basis or the fair market value of the common shares. A mark- to- market election may be made and maintained only if our common shares are regularly traded on a qualified exchange, including The Nasdaq Capital Market. Whether our common shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, a U. S. shareholder might not be eligible to make a mark- to-market election to mitigate the adverse tax consequences if we are characterized as a PFIC. Election Tax Risks. Certain economic risks are inherent in making either a QEF Election or a mark- to- market election. If a QEF Election is made, it is possible that earned income will be reported to a U. S. shareholder as taxable income and income taxes will be due and payable on such an amount. A U. S. shareholder of our common shares may pay tax on such " phantom " income, i. e., where income is reported to it pursuant to the QEF Election, but no cash is distributed with respect to such income. There is no assurance that any distribution or profitable sale will ever be made regarding our common shares, so the tax liability may result in a net economic loss. A mark- to- market election may result in significant share price gains in one year causing a significant income tax liability. This gain may be offset in another year by significant losses. If a mark- to- market election is made, this highly variable tax gain or loss may result in substantial and unpredictable changes in taxable income. The amount included in income under a mark- to- market election may be substantially greater than the amount included under a QEF election. Both the QEF and mark-to- market elections are binding on the U. S. shareholder for all subsequent years that the U. S. shareholder owns our shares unless permission to revoke the election is granted by the IRS. Purging Election. Although we generally will continue to be treated as a PFIC as to any U. S. shareholder if we are a PFIC for any year during a U. S. shareholder' s holding period, if we cease to satisfy the requirements for PFIC classification, the U. S. shareholder may avoid PFIC classification for subsequent years if the U. S. shareholder elects to make a so- called " purging election, " by recognizing income based on the unrealized appreciation in the common shares through the close of the tax year in which we cease to be a PFIC. When a foreign corporation no longer qualifies as a PFIC (due to a change in facts or law), the foreign corporation nonetheless retains its PFIC

status with respect to a shareholder unless and until the shareholder makes an election under Code section 1298 (b) (1) and regulations section 1. 1298 – 3 (purging election) on IRS Form 8621 attached to the shareholder' s tax return (including an amended return), or requests the consent of the IRS Commissioner to make a late election under Code section 1298 (b) (1) and regulations section 1. 1298 – 3 (e) (late purging election) on Form 8621- A. RULES RELATING TO A PFIC ARE VERY COMPLEX. YOU SHOULD CONSULT YOUR TAX ADVISER CONCERNING THE RELATIVE MERITS AND THE ECONOMIC AND TAX IMPACT OF THE PFIC RULES TO YOUR INVESTMENT IN OUR COMMON SHARES AS A NON- ELECTING U. S. SHAREHOLDER, A U. S. SHAREHOLDER MAKING A QEF ELECTION, A U. S. SHAREHOLDER MAKING A MARK- TO- MARKET ELECTION, OR A U. S. SHAREHOLDER MAKING ANY AVAILABLE PURGING ELECTION. Should we be classified as a PFIC during a U. S. shareholder' s holding period for our common shares, each such U. S. shareholder should consult their own tax advisors with respect to the possibility of making these elections and the U. S. federal income tax consequences of the acquisition, ownership and disposition of our common shares. In addition, the possibility of us being classified as a PFIC may deter certain U. S. investors from purchasing our common shares, which could have an adverse impact on the market price of our common shares and our ability to raise additional financing by selling equity securities, including our common shares. It may be difficult for non- Canadian shareholders or investors to obtain and enforce judgments against us because of our organization as a British Columbia corporation. We are a corporation governed under the BCBCA. Two of our directors are residents of Canada, and all or a substantial portion of their assets, and a small portion of our assets, are located outside the United States. Consequently, it may be difficult for holders of our securities who reside in the United States to effect service within the United States upon those directors who are not residents of the United States. It may also be difficult for holders of our securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon our civil liability and the civil liability of our directors, and officers under the United States federal securities laws. Our shareholders and other investors should not assume that British Columbian or Canadian courts (i) would enforce judgments of United States courts obtained in actions against us or such directors, or officers predicated upon the civil liability provisions of the United States federal securities laws or the securities or " blue sky " laws of any state or jurisdiction of the United States, or (ii) would enforce, in original actions, liabilities against us or such directors, or officers predicated upon the United States federal securities laws or any securities or " blue sky " laws of any state or jurisdiction of the United States. In addition, the protections afforded by the securities laws of British Columbia or Canada may not be available to our shareholders or other investors in the United States. General Risk Factors 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 we expect to occur, such as the anticipated number of clinical sites and pace of enrollment **and the timing of the interim analysis** for our ReMEDy2 **trial and the timing of completion of the PE** trial. 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 significantly from what has been publicly disclosed. The projected timing of events such as the anticipated number of clinical sites and pace of enrollment for our ReMEDy2 trial or the filing of an application to obtain regulatory approval or an announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing or events that we anticipate may occur as a result of different factors, including regulatory actions, the nature of the results obtained during a clinical trial or during a research phase, problems with a ~~CMO~~ **CDMO** or **CRO** ~~contract research organization~~, health crises, epidemics or pandemics, full or partial clinical holds that may be imposed by the FDA or any other event having the effect of delaying the publicly announced timeline or leading to results that are different from what we expect. We undertake no obligation to update or revise any forward- looking information, 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 or changes in other events of which we anticipate could have a material adverse effect on our business plan, financial condition or operating results, and the trading price of our common shares. If securities or industry analysts do not continue to publish research or reports about our business, or publish negative reports about our business, the market price of our common shares and trading volume could decline. The market price and trading volume for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our common shares or negatively change their opinion of our common shares, the market price of our common shares would likely decline. If one or more of these analysts cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our common shares or trading volume to decline. We, or our third- party contract research organizations or consultants, may be subject to information technology **(IT)** systems failures, network disruptions, breaches in data security and computer crime and cyber- attacks, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. We are ~~increasingly~~ dependent upon **IT** ~~information technology~~ systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third- party consultants who have access to our confidential information. **IT** ~~Information technology~~ system failures, network disruptions, breaches of data security and sophisticated and targeted computer crime and cyber- attacks could disrupt our operations by impeding our ~~drug~~ development programs, including delays in our ~~regulatory efforts~~ **clinical trials**, the manufacture or shipment of **our drug** ~~products~~ **product candidate or other clinical supplies**, the processing of transactions or reporting of financial results, or by causing an unintentional disclosure of

confidential information. Despite our security measures, our **IT** ~~information technology~~ and infrastructure may be ~~vulnerable to attacks~~ **attacked** by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. In the ordinary course of our business, we collect and store sensitive data on our network, including ~~IP~~ **intellectual property**, proprietary business information, and personal information of our business partners and employees. Despite our efforts to protect sensitive, confidential or personal data or information, our facilities and systems and those of our third- party service providers may **experience** ~~be vulnerable to~~ security breaches, theft, misplaced or lost data, programming and / or human errors that could potentially lead to the compromising of sensitive, confidential or personal data or information, improper use of our systems, software solutions or networks, unauthorized access, use, disclosure, modification or destruction of information, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, ~~competitiveness~~ **clinical trials** and results of operations **. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate for these events on a timely basis, we may suffer interruptions in our ability to manage our clinical trials and other operations. In addition, we and the third parties on which we rely may be more susceptible to security breaches and other security incidents due to many of our and their employees working remotely for some portion of time. While management has taken steps to address these concerns by conducting employee training, implementing certain data and system redundancy, hardening and fail- over along with other network security, comprehensive monitoring of our networks and systems, maintenance of backup and protective systems and other internal control measures, there can be no assurance that the measures we have implemented to date would be sufficient in the event of a system failure, loss of data or security breach. Because the techniques used to obtain unauthorized access change frequently and can be difficult to detect, anticipating, identifying or preventing these intrusions or mitigating them if and when they occur may be challenging** . Although we have been the target of cyber attacks and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication, the aggregate impact of these attacks on our operations and financial condition has not been material ~~to date~~ . **However** ~~In addition~~ , ~~we and~~ **in light of** the **fact that** ~~third parties on which we rely may be more susceptible to security~~ **cybersecurity** ~~breaches~~ **threats have been rapidly evolving in sophistication** and **prevalence** ~~other security incidents due to many of our and their employees working remotely for some portion of time. While management has taken steps to address these concerns by conducting employee training~~ , ~~implementing certain data and system redundancy, hardening and fail- over along with other network security, comprehensive monitoring of our networks and systems, maintenance of backup and protective systems and other internal control measures, there can be~~ no assurance **can be provided** that ~~the measures~~ we ~~have implemented~~ **will not become subject** to ~~date would be sufficient in~~ **future attacks, especially when our cybersecurity protection is dependent at least to some extent on** the **lack of human error. SEC rules related to cybersecurity risk management may further increase our regulatory burden and the cost of compliance in such** ~~event~~ **events** ~~of a system failure, loss of data or security breach~~ . As a result, in the event of such a failure, loss of data or security breach, our financial condition and operating results could be adversely affected **. We currently use limited traditional and generative artificial intelligence (AI) solutions for certain administrative and other functions. We may incorporate additional AI solutions into our information systems in the future and these solutions may become important in our operations over time. The ever- increasing use and evolution of technology, including cloud- based computing and AI, creates opportunities for the potential loss or misuse of personal data that we use to run our business, and unintentional dissemination or intentional destruction of confidential information stored in our or our third party providers' systems, portable media or storage devices, which may result in significantly increased business and security costs, a damaged reputation, administrative penalties, or costs related to defending legal claims** . We could be subject to securities class action litigation, which is expensive and could divert management attention. In the past, securities class action litigation has often been brought against a company following a significant decline or increase in the market price of its securities or certain significant business transactions. We may become involved in this type of litigation in the future, especially if our clinical trial results are not successful or we enter into an agreement for a significant business transaction. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and our resources, which could harm our business. This is particularly true in light of our limited securities litigation insurance coverage. ~~A variety of risks are associated with operating our business internationally which could materially adversely affect our business. In the past, we have conducted R & D operations and / or clinical trials in the United States, Canada and Australia. In the future, we expect to conduct certain clinical trials, and plan to seek regulatory approval of DM199, or any future product candidates, outside of the United States. Accordingly, we will be subject to risks related to operating in foreign countries including, among others: ● differing regulatory requirements for drug approvals; ● different standards of care in various countries that could complicate the design of our clinical trials and / or the evaluation of our product candidates; ● different reimbursement systems and different competitive drugs indicated to treat the indications for which our product candidates are or will be developed; ● different United States and foreign drug import and export rules; ● reduced protection for intellectual property rights in certain countries; ● withdrawal from, or revision to or unexpected changes in international trade policies or agreements and the imposition or increases in import and export licensing and other compliance requirements, customs duties and tariffs, import and export quotas and other trade restrictions, license obligations, and other non- tariff barriers to trade; ● the imposition of U. S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with that country, company, person or entity; ● 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; ● compliance with the Foreign Corrupt Practices Act and other anti- corruption and anti- bribery laws; ● foreign taxes, including withholding of payroll taxes; ● foreign currency exchange rate fluctuations, which could result in increased operating**

~~expenses and / or reduced revenue, and other obligations incident to doing business in another country; ● difficulties in managing and staffing international operations and increases in infrastructure costs, including legal, tax, accounting, and information technology; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● production shortages or shipping delays resulting from any events affecting raw material supply or manufacturing capabilities abroad, such as supply chain disruptions, closures and slowdowns caused by COVID- 19; ● potential liability resulting from development work conducted by foreign partners or collaborators; ● transportation delays and interruptions; ● business interruptions resulting from natural disasters or geopolitical actions, including war, such as the current war between Russia and Ukraine and the conflict between Israel and Hamas, and terrorism or systems failure, including cybersecurity breaches; and ● compliance with evolving and expansive international data privacy laws, such as the European Union General Data Protection Regulation. We face the risk of product liability claims, which could exceed our insurance coverage, deplete our cash resources and lead to clinical trial delays. A risk of product liability claims, and related negative publicity, is inherent in the development of human therapeutics. We are exposed to the risk of product liability claims alleging that use of DM199, or any future product candidate, caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of a product candidate and may be made directly by patients involved in clinical trials of our product candidate, by consumers, healthcare providers or by individuals, organizations or companies selling our products, if and when approved. Product liability claims can be expensive to defend, even if the product or product candidate did not actually cause the alleged injury or harm, and could lead to clinical trial delays and could negatively impact existing or future collaborations. Insurance covering product liability claims becomes increasingly expensive as a product candidate moves through the development pipeline to commercialization. To protect against potential product liability risks, we carry product liability insurance coverage at a level we deem appropriate for our stage of development. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaboration agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources, and otherwise have a material adverse effect on our business, financial condition, and results of operations. If we are unable to maintain product liability insurance required by third parties, certain agreements, such as those with clinical trial sites, contract research organizations and other supporting vendors, would be subject to termination, which could have a material adverse impact on our operations. Some of our agreements with third parties require, and in the future will likely require, us to maintain product liability insurance in at least certain specified minimum amounts. If we cannot maintain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations.~~ Our insurance policies are expensive and protect us only from certain business risks, which could leave us exposed to significant uninsured liabilities. Additionally, future fluctuations in insurance cost and availability could adversely affect our operating results or risk management profile. We hold a number of insurance policies, including, but not limited to, product and general liability insurance, directors' and officers' liability insurance, property insurance **,** and workers' compensation insurance. The costs of maintaining adequate insurance coverage, most notably directors' and officers' liability insurance, have increased significantly ~~during~~ **in** the ~~last~~ **past** ~~few years~~ and **could** ~~may continue to~~ do so **again** in the future, thereby adversely affecting our operating results. If such costs increase, we may be forced to accept lower coverage levels and higher deductibles, which, in the event of a claim, could require significant, unplanned expenditures of cash, which could adversely affect our business. Future potential directors and officers could view our directors' and officers' liability insurance coverage as limited or even inadequate. Limited directors' and officers' liability insurance coverage, or the perception that our directors' and officers' liability insurance coverage is inadequate, may make it difficult to attract and retain directors and officers, and we may lose potential independent board members and management candidates to other companies that have more extensive directors' and officers' liability insurance coverage. In addition, if any of our current insurance coverages should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. ~~Scrutiny~~ **The widespread outbreak of communicable diseases could delay our clinical trials** and ~~evolving expectations~~ **otherwise materially and adversely affect our business, operating results and financial condition. We face risks related to health epidemics or outbreaks of communicable diseases, for example, the outbreak around the world of the highly transmissible and pathogenic coronavirus COVID- 19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries. Many countries around the world may impose quarantines and restrictions on travel and mass gatherings to slow the spread of communicable diseases and close non- essential businesses. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could delay our clinical trials and materially affect our business, operating results and financial condition. A pandemic or outbreak could result in difficulty securing additional clinical trial site locations, and adversely affect the ability of investigators and other study staff enrolling participants and may also adversely impact the ability of activities of CROs, trial monitors, laboratories and other critical vendors and consultants supporting our clinical trials. The potential negative impacts also include the inability to have study visits at trial sites, incomplete collection of safety and efficacy data, and higher rates of drop- out of subjects** from ~~regulators~~ **ongoing trials** , ~~investors and~~ **delays in site entry of study data into** ~~other~~ -- **the data base** ~~stakeholders with respect to our environmental~~ , **delays in monitoring of trial data because of restricted physical access** ~~social and governance practices may impose additional costs on us or expose us~~ to **sites** ~~new or additional risks. Companies are facing scrutiny from regulators~~ , **delays in site responses** ~~investors, and other stakeholders related~~ to **queries** ~~their environmental~~ , **delays in data** ~~social and governance (ESG) practices and disclosure. For~~

~~example, during 2022, the SEC proposed new climate disclosure rules, which, if adopted, would require new climate~~ **base lock** ~~related disclosure in SEC filings~~, ~~including certain climate~~ **delays in data analyses, delays in time to top** ~~-~~ **line** ~~related metrics and greenhouse gas emissions~~ data, ~~information about climate- related targets~~ and **delays in completing study reports** ~~goals, transition plans, if any, and extensive attestation requirements~~. In addition ~~to requiring companies to quantify~~ **, outbreaks or the perception of** ~~and~~ ~~-~~ **an outbreak near a clinical trial site location** ~~disclose direct emissions data, the new rules also would~~ **could** ~~require disclosure of climate~~ impact ~~arising from~~ the **willingness** ~~operations and uses by the company's business partners and contractors and end- users~~ of **participants to enroll in** ~~the company's products and / or~~ **our** ~~services. We are currently~~ ~~--~~ **current or future clinical trials. These situations could cause delays in our clinical trial plans and increase expected** ~~assessing the impact of the new rules, if adopted as proposed, but at this time, we cannot predict the~~ costs ~~of implementation or any potential adverse impacts resulting from the new rules if adopted. However~~, **all** ~~we may incur increased costs relating to the assessment and disclosure of climate- related risks and increased litigation risks related to disclosures made pursuant to the new rules, either~~ of which could **have a** ~~materially~~ ~~--~~ **material** ~~and adversely~~ ~~--~~ **adverse** ~~affect~~ **effect on** our ~~future~~ **business, prospects, operating** results ~~of operations~~ and financial condition. ~~Further~~ **Additionally**, ~~investor advocacy groups, investment funds and influential investors are also increasingly focused on these~~ ~~--~~ **the** ~~practices~~ **manufacturing of DM199 and other product candidates**, ~~especially~~ as ~~they~~ **well as other clinical supplies required to conduct our studies may be delayed by** ~~relate~~ **related** ~~to the environment, climate change, health and safety,~~ supply chain ~~management~~ **issues**, **specifically** ~~diversity, labor conditions and human rights, both in our own operations and in our~~ supply ~~chain~~ **of raw materials, compounded by international shipping delays**. **Further, a widespread pandemic** ~~Increased ESG- related compliance costs~~ could result in **significant disruption** ~~material increases to our overall operational costs. Our ESG practices may not meet the standards~~ of **global financial markets** ~~all of our stakeholders and advocacy groups may campaign for further changes. A failure~~, **reducing** ~~or~~ **our ability** ~~perceived failure,~~ to ~~adapt to~~ **access capital and negatively affect** ~~or~~ **our liquidity. In addition, it** ~~comply with regulatory requirements or to respond to investor or stakeholder expectations and standards~~ could **materially affect** ~~negatively impact our business and reputation and have a negative impact on~~ the **value** ~~trading price~~ of our common shares ~~. We no longer qualify as an emerging growth company, and as a result, we now have to comply with increased public company disclosure and compliance requirements, which may have a negative impact on our business and results of operations. We no longer qualify as an emerging growth company. As such, we are now subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. While we remain a smaller reporting company and are still subject to certain scaled disclosure requirements, we expect that the loss of emerging growth company status may still increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements, all of which may have a negative impact on our business and results of operations~~. Our business or the value of our common shares could be negatively affected as a result of actions by activist shareholders. We value constructive input from our shareholders, and our Board of Directors and management team are committed to acting in the best interests of our shareholders. However, shareholders may from time to time engage in proxy solicitations, advance shareholder proposals or otherwise attempt to effect changes or acquire control over the Company. Responding to proxy contests and other actions by activist shareholders can be costly and time- consuming, disrupting our operations and diverting the attention of our Board of Directors and senior management from the pursuit of business strategies. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist shareholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, employees, and joint venture partners, and cause our ~~stock~~ **share** price to experience periods of volatility or stagnation. Item 1B. Unresolved Staff Comments