

## Risk Factors Comparison 2024-09-30 to 2023-09-29 Form: 10-K

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Summary of Risk Factors The following is a summary of material risks that could affect the Company. This summary may not contain all of our material risks, and it is qualified in its entirety by the more detailed risk factors set forth below. • Our IntegraSyn manufacturing approach may prove unsuccessful in achieving yields and / or cost levels required to be economically competitive with alternative methods of manufacturing. • Our prospects depend on the success of our Product Candidates, which are **at in the** early –stages of development with a statistically high probability of failure and are subject to lengthy, time-consuming and inherently unpredictable regulatory processes. • ~~Even if our Product Candidates advance through preclinical studies and clinical trials, we may experience difficulties in managing our growth and expanding our operations. • If we have difficulty enrolling patients in clinical trials, the completion of the trials may be delayed or cancelled. • If clinical trials of our Product Candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our Product Candidates. • If we experience delays in clinical testing, we will be delayed in commercializing our Product Candidates, and our business may be substantially harmed. • Negative results from clinical trials or studies of others and adverse safety events involving the targets of our products may have an adverse impact on our future commercialization efforts.~~ • We intend to expend our limited resources to pursue our Product Candidates for certain indications and may fail to capitalize on other Product Candidates or other indications for our Product Candidates that may be more profitable or for which there is a greater likelihood of success. • **Our Product Candidates contain compounds that may be classified as “ controlled substances ”, the use of which may generate public controversy and restrict their development or commercialization. • Any actual or threatened delisting of our securities by Nasdaq due to our inability to satisfy applicable listing standards, including compliance with the minimum bid price rule, could have a material and adverse effect on our business, operations and financial condition, and the liquidity and value of our securities. • Research restrictions, product shipment delays or prohibitions could have a material adverse effect on our business, results of operations and financial condition. • Our relationships with customers and third- party payors are subject to applicable anti- kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to, among other things, sanctions, penalties, damages, reputational harm and diminished profits and future earnings. • Our insurance may be insufficient to cover losses that may occur as a result of our operations. • There may be changes in laws, regulations and guidelines which are detrimental to our business. • Controlled substance legislation may differ in other jurisdictions and could restrict our ability to market our products internationally, which could materially and adversely affect our financial results. • Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. • Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. • The market prices for our common shares, no par value (the “ Common Shares ”), are volatile and are anticipated to fluctuate in the near term. • Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or Product Candidates. • Future offerings of debt or equity securities may rank senior to our Common Shares. • For as long as we are an “ emerging growth company ” we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our Common Shares being less attractive to investors and could make it more difficult for us to raise capital. • If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our Common Shares. • Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. • Deficiencies in disclosure controls and procedures and internal control over financial reporting could result in a material misstatement in our financial statements, and our ability to identify and effectively remediate any such material weaknesses that could have a material and adverse effect. • In connection with the audit of our financial statements as of and for the year ended June 30, 2023, a material weakness in our internal control over financial reporting was identified and we may identify additional material weaknesses in the future. • Future sales and issuances of, and rights to purchase, our Common Shares, including by officers and directors could materially dilute the percentage ownership of our shareholders and may cause our share price to fall. • We (i) have incurred significant losses since our inception and (ii) anticipate we will incur losses in the future, and our operating losses have raised substantial doubt regarding our ability to continue as a going concern • We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our Product Candidates. • We currently have limited commercial revenue and may never become profitable. • Our success is largely dependent upon our patents, proprietary technology, and other intellectual property. • 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. • We may become subject to claims or become involved in lawsuits related to intellectual property. • We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time**

consuming and unsuccessful, and materially and adversely effect our business. • If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished. • We may not be able to protect our intellectual property rights throughout the world. • Patent terms may be inadequate to protect our competitive position on our Product Candidates. • Intellectual property rights do not necessarily address all potential threats to our competitive advantage. • We rely heavily on contract manufacturers over whom we have limited control and our existing collaboration agreements and any that we may enter into in the future may not be successful. Investing in our Common Shares involves a high degree of risk. Therefore, you should carefully consider each of the following risks, together with all other information set forth in this Annual Report, including the consolidated financial statements and the related notes, before making a decision to buy our Common Shares. If any of the following risks actually occurs, our business could be harmed. In that case, the trading price of our Common Shares could decline, and you may lose all or part of your investment. Risks Related to our Business and Industry Our prospects depend on the success of our Product Candidates which are at early stages of development with a statistically high probability of failure. Given the Company's early stage of development, we can make no assurance that our research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, we, alone or with others, must successfully develop, gain regulatory approval, and market our future products. We currently have no products that have been approved by the FDA, HC, or any similar regulatory authority. To obtain regulatory approvals for our Product Candidates being developed and to achieve commercial success, clinical trials must demonstrate that the Product Candidates are safe for human use and that they demonstrate efficacy. We have no products or technologies which are currently in human clinical trials. Additionally, we have no products for commercial sale or licensed for commercial sale, nor do we expect to have any such products for the next several years. Many potential pharmaceuticals products never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Our Product Candidates may fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Positive results of early preclinical research may not be indicative of the results that will be obtained in later stages of preclinical or clinical research. Similarly, positive results from early-stage clinical trials may not be indicative of favorable outcomes in later-stage clinical trials. We can make no assurance that any future studies, if undertaken, will yield favorable results. The early stage of our product development makes it particularly uncertain whether any of our product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of our Product Candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed. If we are successful in developing our current and future Product Candidates into approved products, we will still experience many potential obstacles, such as the need to develop or obtain manufacturing, marketing and distribution capabilities. If we are unable to successfully commercialize any of our products, our financial condition and results of operations may be materially and adversely affected. Even if our Product Candidates advance through preclinical studies and clinical trials, we may experience difficulties in managing our growth and expanding our operations. We have limited resources to carry out objectives for our current and future preclinical studies and clinical trials. Since our inception as a pharmaceutical company in October 2014, we have conducted numerous preclinical experiments and are currently conducting early-stage clinical trials, which is a time-consuming, expensive and uncertain process. In addition, while we have experienced management and expect to contract out many of the activities related to conducting these programs, we are a small company with less than 15 employees and, therefore, have limited internal resources both to conduct preclinical studies and clinical trials and to monitor third-party providers. As our Product Candidates advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing operations, either by expanding our internal capabilities or contracting with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. Any actual or threatened delisting of our securities by Nasdaq could have a material and adverse effect on our business, operations and financial condition, and could, among other things, limit investors' ability to make transactions in our securities and subject us to additional trading restrictions. As previously reported by the Company, on March 19, 2024, the Company received written notification from the Listing Qualifications Department of Nasdaq that the Company has been granted an additional 180-day compliance period, or until September 16, 2024 (the "Extended Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement for the continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550 (a) (2) (the "Minimum Bid Price Rule"). Nasdaq's determination was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the bid price requirement, and the Company's written notice of its intention to consider all available options to regain compliance during the Extended Compliance Period, including, if necessary, effecting a reverse stock split. The Company was unable to regain compliance during the Extended Compliance Period and on September 17, 2024, the Company received an additional notification from the Listing Qualifications Department stating that due to the deficiency, the Company's securities would be delisted from Nasdaq on September 26, 2024, unless the Company appealed Nasdaq's determination to a Hearings Panel (the "Panel"). A hearing request would stay the suspension of the Company's securities pending the Panel's discussion. On September 17, 2024, the Company submitted the hearing request to appeal (the "Appeal Request") Nasdaq's determination before

the Panel. The hearing will take place on October 31, 2024 and it is anticipated that the Panel's decision will follow shortly thereafter. The pendency of the Appeal Request does not have an immediate effect on the listing of our Common Shares and our Common Shares will continue to trade on Nasdaq under the symbol "INM". While the Company has filed the Appeal Request, there can be no assurances, however, that we will be successful in regaining compliance with the continued listing requirements and maintaining the listing of our Common Shares on Nasdaq. Delisting from Nasdaq could materially and adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our securities, including our Common Shares. The actual or threatened delisting of our securities could also have other material and adverse consequences, including the potential loss of confidence by employees and other stakeholders, the loss of institutional investor interest and fewer business development opportunities, limited availability of market quotations for our securities, reduced liquidity with respect to our securities, a determination that our Common Shares is "penny stock," which will require brokers trading in shares of our Common Shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of our Common Shares, and limited amount of news and analyst coverage of the Company. To the extent that our Common Shares became eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their Common Shares or obtain accurate quotations as to the market value of our Common Shares. Furthermore, the National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our Common Shares are currently listed on Nasdaq, such securities will be deemed covered securities. Although the states will be preempted from regulating the sale of our securities, the federal statute does allow states to investigate companies if there is a suspicion of fraud and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Additionally, if we were no longer listed on Nasdaq, our securities would not be covered securities and we would be subject to regulations in each state in which we offer our securities. If we have difficulty enrolling patients in clinical trials, the completion of the trials may be delayed or cancelled. As our Product Candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients that meet the eligibility criteria for those trials. The factors that affect our ability to enroll patients are largely uncontrollable and include, but are not limited to, the following: • size and nature of the patient population; • inclusion and exclusion criteria for the trial; • design of the study protocol; • competition with other companies for clinical sites or patients; • the perceived risks and benefits of the product candidate under study; • the patient referral practices of physicians; and • the number, availability, location and accessibility of clinical trial sites. As a result of the foregoing factors, we may have difficulty enrolling or maintaining the enrollment of patients in any clinical trials conducted for our products, which may result in the delay or cancellation of such trials. The delay or cancellation of any clinical trials could shorten any periods during which we may have the exclusive right to commercialize our Product Candidates or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our Product Candidates and may harm our financial condition, results of operations and prospects. If clinical trials of our Product Candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our Product Candidates. Before obtaining marketing approval from regulatory authorities for the sale of our Product Candidates, we must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the Product Candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do 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, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our Product Candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our Product Candidates under development will successfully gain market approval from the FDA or other regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing. If we experience delays in clinical testing, we will be delayed in commercializing our Product Candidates, and our business may be substantially harmed. We cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our Product Candidates or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our Product Candidates and may harm our financial condition, results of operations and prospects. The commencement and completion of clinical trials for our products may be delayed for a number of reasons, including delays related, but not limited, to: • failure by regulatory authorities to grant permission to proceed or placing the clinical trial on hold; • import / export and research restrictions for cannabinoid-based pharmaceuticals may delay or prevent clinical trials in various geographical jurisdictions; • patients failing to enroll or remain in our trials at the rate we expect; • suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of our contract

manufacturers to comply with current good manufacturing practice (“ cGMP ”) requirements; • any changes to our manufacturing process that may be necessary or desired; • delays or failure to obtain clinical supply from contract manufacturers of our products necessary to conduct clinical trials; • Product Candidates demonstrating a lack of safety or efficacy during clinical trials; • patients choosing an alternative treatment for the indications for which we are developing any of our Product Candidates or participating in competing clinical trials and / or scheduling conflicts with participating clinicians; • patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons; • reports of clinical testing on similar technologies and products raising safety and / or efficacy concerns; • clinical investigators not performing our clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner; • failure of our CROs, to satisfy their contractual duties or meet expected deadlines; • inspections of clinical trial sites by regulatory authorities or 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 a clinical hold on the entire study; • one or more IRBs or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or • failure to reach agreement on acceptable terms with prospective clinical trial sites. Our product development costs will increase if we experience delays in testing or approval or 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 study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to regulatory authorities or IRBs or ethics committees for re- examination, which may impact the cost, timing or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on our business, financial condition and prospects. Our IntegraSyn manufacturing approach may prove unsuccessful in achieving yields and / or cost levels required to be economically competitive with alternative methods of manufacturing. Given the early stage of development of the IntegraSyn program and the risks inherent in research and development, it is too early to project the commercial viability of cannabinoids produced via this process. Potential negative outcomes from this program include but are not limited to: • the technology fails to produce sufficient quantities of cannabinoids or ones for which we or others have a need; or • the cost structure of the technology is such that it is not commercially competitive with alternate methods of cannabinoid manufacturing leading to the technology having no value proposition nor incremental value to the Company. Negative results from clinical trials or studies of others and adverse safety events involving the targets of our products may have an adverse impact on our future commercialization efforts. From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to our Product Candidates, or the therapeutic areas in which our Product Candidates compete, could adversely affect the price of our Common Shares and our ability to finance future development of our Product Candidates, and our business and financial results could be materially and adversely affected. We intend to expend our limited resources to pursue our Product Candidates for certain indications and may fail to capitalize on other Product Candidates or other indications for our Product Candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we are focusing on research programs relating to our Product Candidates for certain indications, primarily for the treatment of EB, which concentrates the risk of product failure in the event our Product Candidates prove to be unsafe or ineffective or inadequate for clinical development or commercialization. As a result, we may forego or delay pursuit of opportunities with other Product Candidates or for other indications that could later prove to have greater commercial potential. We may also deem it advisable to refocus our clinical development programs based on clinical trial results. The regulatory approval processes of the FDA, HC, the EMA and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our Product Candidates, our business will be substantially harmed. We are not permitted to market our Product Candidates in any jurisdiction until we receive formal approval from the appropriate regulatory authorities. For example, prior to submitting an NDA to the FDA or an MAA to the EMA for approval of our Product Candidates, we will need to complete our preclinical studies and clinical trials. Successfully completing our clinical program and obtaining approval of an application seeking commercialization approval is a complex, lengthy, expensive and uncertain process, and the regulatory authorities may delay, limit or deny approval of our Product Candidates for many reasons, including, among others, because: • process and the regulatory authorities may delay, limit or deny approval of our Product Candidates for many reasons, including, among others, because: • we may not be able to demonstrate that our Product Candidates are safe and effective in treating patients to the satisfaction of the regulatory authorities such as the FDA, HC or EMA; • the results of our clinical trials may not meet the level of statistical or clinical significance required by the regulatory authorities for marketing approval; • the regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials; • the regulatory authorities may require that we conduct additional clinical trials; • the regulatory authorities or other applicable foreign regulatory authorities may not approve the formulation, labeling or specifications of our Product Candidates; • the contract manufacturing organizations and other contractors that we may retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials; • the regulatory authorities may find the data from clinical studies and clinical trials insufficient to demonstrate that our Product Candidates are safe and effective for their proposed indications; • the regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical trials; • the regulatory authorities may not accept

data generated at our clinical trial sites or may disagree with us over whether to accept efficacy results from clinical trial sites outside the United States, Canada or outside the European Union, as applicable, where the standard of care is potentially different from that in the United States, Canada or in the European Union, as applicable; ● if our applications are submitted to the regulatory authorities, the regulatory authorities may have difficulties scheduling the necessary review meetings in a timely manner, may recommend against approval of our application or may recommend or require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; ● the FDA may require development of a Risk Evaluation and Mitigation Strategy which would use risk minimization strategies to ensure that the benefits of certain prescription drugs outweigh their risks, as a condition of approval or post-approval, and the EMA may grant only conditional marketing authorization or impose specific obligations as a condition for marketing authorization, or may require us to conduct post-authorization safety studies; ● the FDA, DEA, HC, EMA or other applicable foreign regulatory agencies may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract or DEA or other applicable foreign regulatory agency quotas may limit the quantities of controlled substances available to our manufacturers; or ● the FDA, HC, EMA or other applicable foreign regulatory agencies may change their approval policies or adopt new regulations. In the United States, our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including, among others, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services ( ~~or~~ “ HHS ” ), (for example, the Office of Inspector General), the Department of Justice ( ~~or~~ “ DOJ ” ), and individual United States Attorney offices within the DOJ, and state and local governments. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private “ qui tam ” actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. Any of these factors, many of which **are beyond our control, could increase development costs, jeopardize our ability to obtain regulatory approval for and successfully market our Product Candidates and generate product revenue.** We intend to conduct clinical trials for our Product Candidates in several international jurisdictions, and acceptance by all regulatory authorities for such “ international ” data is not certain. ● **Our Product Candidates contain compounds that..... international ” data is not certain.** We intend to conduct clinical trials for our Product Candidates both inside and outside the United States. To date, all of our clinical development has been conducted outside of the United States. Ultimately, we plan to submit NDAs for our Product Candidates to the FDA and other regulatory authorities upon completion of all requisite clinical trials. As an example, although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the clinical trial must be conducted in accordance with FDA regulations relating governing human subject protection and the conduct of clinical trials, which are referred to as “ Good Clinical Practice ” ( ~~or~~ “ GCP ” ) requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U. S. patient population and U. S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance the FDA or any other regulatory authorities will accept data from clinical trials conducted outside of the United States or other international jurisdictions. If the FDA or any other regulatory authorities does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan. In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include: ● foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials; ● administrative burdens of conducting clinical trials under multiple foreign regulatory schema; ● foreign currency fluctuations which could negatively impact our financial condition since certain payments are paid in local currencies; ● manufacturing, customs, shipment and storage requirements; ● cultural differences in medical practice and clinical research; and ● diminished protection of intellectual property in some countries. Our Product Candidates contain compounds that may be classified as “ controlled substances ”, the use of which may generate public controversy and restrict their development or commercialization. If a drug has a potential for abuse, the NDA or other regulatory submission must include a description and analysis of studies or information related to abuse of the drug, including a proposal for scheduling (for example, in the U. S. under the federal Controlled Substances Act ( ~~or~~ “ CSA ” ). A description of any studies related to overdose is also required, including information on dialysis, antidotes, or other treatments, if known. While we believe there would be relatively minimal abuse potential with our Product Candidates given the low drug concentration and topical route of administration, we could be incorrect or they may be perceived as having the potential for substance abuse. In either case, there may be a negative effect on our ability to successfully develop or commercialize our Product Candidates. Since

our Product Candidates contain purified substances that are chemically identical to those occurring in nature, they may, therefore, be classified as “ controlled substances ”, and their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our Product Candidates. These pressures could also limit or restrict the introduction and marketing of our Product Candidates. Despite that fact that our APIs, which are the ingredients that give medicines their effects, are synthetically made and, therefore, we have no interaction with the Cannabis plant, adverse publicity from Cannabis misuse or adverse side effects from Cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable for our Product Candidates. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed. Furthermore, if our Product Candidates are classified as “ controlled substances ”, they may be subject to import / export and research restrictions that could delay or prevent the development of our products in various geographical jurisdictions. The successful commercialization of our Product Candidates may require permits or approvals from regulatory bodies, such as the DEA, that regulate controlled substances. **If any of our Product Candidates receives marketing approval and we or others later identify undesirable side effects caused by the Product Candidate, our ability to market and derive revenue from the product candidates could be compromised. In the event that any of our Product Candidates receive regulatory approval and we or others identify undesirable side effects caused by one of our products, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business: (i) regulatory authorities may withdraw their approval of the product or seize the product; (ii) we may be required to recall the product or change the way the product is administered to patients; (iii) additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; (iv) we may be subject to fines, injunctions or the imposition of civil or criminal penalties; (v) regulatory authorities may require the addition of labeling statements, such as a “ black box ” warning or a contraindication; (vi) we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients; (vii) we could be sued and held liable for harm caused to patients; (viii) the product may become less competitive; and (ix) our reputation being harmed.** Research restrictions, product shipment delays or prohibitions could have a material adverse effect on our business, results of operations and financial condition. Research on and the shipment, import and export of our Product Candidates and the API used in our Product Candidates will require research permits, import and export licenses by many different authorities. For instance, in the United States, the FDA, U. S. Customs and Border Protection, and the DEA; in Canada, the Canada Border Services Agency, and HC; in Europe, the EMA and the European Commission; in Australia and New Zealand, the Australian Customs and Border Protection Service, the Therapeutic Goods Administration, the New Zealand Medicines and Medical Device Safety Authority and the New Zealand Customs Service; and in other countries, similar regulatory authorities, regulate the research on and import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process ~~requires~~ **require** the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of API and our Product Candidates may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in delays in clinical trials or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our Product Candidates. Once shipment is complete, we or the research contractors we are working with may also suffer further delays or restrictions as a result of regulations governing research on cannabinoids. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our Product Candidates could have a material adverse effect on our business, results of operations and financial condition. The aforementioned examples and lists of various authorities that may currently, or in the future, affect our ability to conduct research on or import or export our Product Candidates and / or API, should not be construed as exhaustive or comprehensive in any way. Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our Product Candidates. Particularly in the United States but also in other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes in recent years regarding the healthcare system that could prevent or delay marketing approval of our Product Candidates, restrict or regulate post- approval activities or affect our ability to profitably sell any Product Candidates for which we obtain marketing approval. Healthcare reform measures that have been and may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and ~~in~~ **in**-additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. **Any Product Candidates we develop may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, thereby materially and adversely impacting our business. The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, drug pricing remains subject to continuing governmental control even after initial approval is granted. Although we intend to monitor these regulations, our programs are currently in the early stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Our ability to commercialize any**

**products also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for pharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.**

Increased scrutiny on drug pricing or changes in pricing regulations could restrict the amount that we are able to charge for our Product Candidates, which could adversely affect our revenue and results of operations. Drug pricing by pharmaceutical companies is currently under increased scrutiny and is expected to continue to be the subject of intense political and public debate in the United States and other jurisdictions. Specifically, there have been several recent U. S. Congressional inquiries and hearings with respect to pharmaceutical drug pricing practices, including in connection with the investigation of specific price increases by several pharmaceutical companies. Additionally, several states have recently passed laws designed to, among other things, bring more transparency to drug pricing, and other states may pursue similar initiatives in the future. We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, increased scrutiny on drug pricing, negative publicity related to the pricing of pharmaceutical drugs generally, or changes in pricing regulations could restrict the amount that we are able to charge for our Product Candidates, which could have a material adverse effect on our revenue and results of operations. **Negative publicity may adversely affect us and our business. Media coverage and public statements that insinuate improper actions by us, regardless of their factual accuracy or truthfulness, may result in negative publicity, litigation or governmental investigations by regulators. Addressing negative publicity and any resulting litigation or investigations may distract management, increase costs and divert resources. Negative publicity may have an adverse impact on our reputation and the morale of our employees, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.**

Even if we are able to commercialize our Product Candidates, they may not receive coverage and adequate reimbursement from third-party payors, which could harm our business. The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford their treatments. Sales of our Product Candidates, if approved, will depend substantially on the extent to which the costs of these Product Candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our Product Candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. In the United States, the Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage available for any of our approved products. Furthermore, private payors often follow Medicare in setting their own coverage policies. Therefore, any reduction in coverage that results from the Medicare Modernization Act may result in a similar reduction from private payors. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ~~or (the~~ “CMS”~~)~~, an agency within the HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. The intended use of a drug product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain. Outside the United States, particularly in EU Member States, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations or the successful completion of Health Technology Assessment ~~(or~~ “HTA”~~)~~ procedures with governmental authorities can take considerable time after receipt of marketing authorization for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines but monitor and control company profits. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce net realized prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our Product Candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be adversely affected. Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, federal exclusion or debarment, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians

and third- party payors play a primary role in the recommendation and prescription of any Product Candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following: ● the U. S. federal healthcare Anti- Kickback Statute impacts our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; ● federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds (including through reimbursement by Medicare or Medicaid or other federal health care programs), which has been applied to impermissible promotion of pharmaceutical products for off- label uses, or making a false statement or record to avoid, decrease or conceal an obligation to pay money to the federal government; ● the U. S. Health Insurance Portability and Accountability Act (~~or~~ "HIPPA"), as amended by the Health Information Technology for Economic and Clinical Health Act (~~or~~ "HITECH Act"), among other things, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services; ● the U. S. federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; ● analogous state laws and regulations, such as state anti- kickback laws, false claims laws and privacy and security of health information laws, may apply to sales or marketing arrangements, claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, or health information; and ● certain state laws require pharmaceutical companies to adopt codes of conduct consistent with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; restrict certain marketing- related activities including the provision of gifts, meals, or other items to certain health care providers; and / or require drug manufacturers to report information related to payments and other transfers of value to physicians and certain other healthcare providers or marketing expenditures. Comparable laws and regulations exist in the countries within the European Economic Area (~~or~~ "EEA"). Although such laws are partially based upon European Union (~~or~~ "EU") law, they may vary from country to country. Healthcare specific, as well as general EU and national laws, regulations and industry codes constrain, for example, our interactions with government officials and healthcare professionals, and the collection and processing of personal health data. Non- compliance with any of these laws or regulations could lead to criminal or civil liability. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Failure to comply with the ~~U. S. Foreign Corrupt Practices Act, or "FCPA", the Canadian Corruption of Foreign Public Officials Act, or "CFPOA",~~ and other global anti- corruption and anti- bribery laws could subject us to penalties and other adverse consequences. The FCPA and the CFPOA, as well as any other applicable domestic or foreign anti- corruption or anti- bribery laws to which we are or may become subject generally prohibit corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity and requires companies to maintain accurate books and records and internal controls, including at foreign- controlled subsidiaries. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Compliance with these anti- corruption laws and anti- bribery laws may be expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, these laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and physicians and other hospital employees are considered to be foreign officials. Certain payments by other companies to hospitals in connection with clinical trials and other work have been deemed to be improper payments to governmental officials and have led to FCPA enforcement actions. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees or agents. We are currently working to get policies and processes in place to monitor compliance with the FCPA and CFPOA. We can make no assurance that they will not engage in prohibited conduct,

and we may be held liable for their acts under applicable anti- corruption and anti- bribery laws. Noncompliance with these laws could subject us to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, whistleblower complaints, reputational harm, adverse media coverage, and other collateral consequences. Any investigations, actions or sanctions or other previously mentioned harm could have a material negative effect on our business, operating results and financial condition. **Recent Any change in export or import controls, anti- corruption laws, economic sanctions or related legislation, or change in the countries, governments, persons, or technologies targeted by such restrictions or legislation, could result in decreased use of our products by customers or in our decreased ability to offer our products internationally, which would harm our business, operating results and financial condition. Furthermore, failure to comply with export or import controls or with anti- corruption or economic sanctions laws may expose us to government investigations, more onerous compliance requirements and significant penalties, which could harm our business, operating results and financial condition. In addition, responding to any action will likely result in a significant diversion of management’ s attention and resources and an increase in professional fees. Enforcement actions and sanctions could harm our business, operating results and financial condition. Trade wars and changes in international trade law and policies may have a material adverse effect on our business, financial condition and results of operations. In October 2022, the Biden administration issued a new set of export controls which (i) banned Chinese companies from buying advanced chips and chip- making equipment in the United States without a license, and (ii) restricted the ability of U. S. persons from providing support for the development or production of chips at certain manufacturing facilities in China. Moreover, in December 2022, the United States imposed new duties on imports from certain major solar panel makers in China after an investigation determined that such manufacturers were avoiding tariffs by finishing their products in Southeast Asian countries. More recently, President Biden signed an executive order that will make it more difficult for U. S. firms to invest in certain Chinese companies — citing national security concerns, the executive order prohibits investments in AI and quantum computing. In response to the foregoing, China implemented its own export controls on two rare elements, germanium and gallium, which the United States relies on to produce chips, fiber optics and solar panels. The ongoing trade war between China and the United States and its potential escalation may have an adverse effect on our business operations and revenues. Starting in April 2018, the United States imposed a 25 % tariff on steel and a 10 % tariff on aluminum imports from other countries. On July 6, 2018, the United States imposed 25 % tariffs on \$ 34 billion worth of Chinese goods. China instituted retaliatory tariffs on certain United States goods. In 2019, the United States and China implemented several rounds of tariff increases and retaliations. On January 15, 2020, the United States and China signed a Phase One trade deal pursuant to which, among other things, the United States will modify existing tariffs. In October 2022, the Biden administration issued a new set of export controls which (i) banned Chinese companies from buying advanced chips and chip- making equipment in the United States without a license, and (ii) restricted the ability of U. S. persons from providing support for the development or production of chips at certain manufacturing facilities in China. 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Since we operate in the United States and deliver products and services to customers in the United States, the trade war could materially and adversely affect us, and especially if, when and to the extent escalated, may cause global economic turmoil and adversely impact the supply chain for our products, the cost of our products and the demand for our products and, thus, may have a material adverse effect on our business and results of operations.** federal Federal legislation and actions by state and local governments may permit reimportation of drugs from / to foreign countries where the drugs are sold at lower prices than in the country of origination, which could materially adversely affect our business and financial condition. We may face competition for our Product Candidates, if approved, from cheaper generics and / or cannabinoid therapies sourced from foreign countries that have placed price controls on pharmaceutical products. This is referred to as parallel importation. For instance, the Medicare Modernization Act contains provisions that may change U. S. importation laws and expand pharmacists’ and wholesalers’ ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U. S. importation laws will not take effect unless and until the Secretary of HHS certifies that the changes will pose no additional risk to the public’ s health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of HHS has so far declined to approve a reimportation plan. Proponents of drug reimportation, including certain state legislatures, may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop, including our Product Candidates, and adversely affect our future revenues and prospects for profitability. We are dependent upon our key personnel to achieve our business objectives. We depend on key personnel, the loss of any of whom could harm our business. Our future performance and development will depend to a significant extent on the efforts and abilities of its executive officers, key employees, and consultants. The loss of the services of one or more of these individuals could harm our business. Our success will depend largely on our continuing ability to attract, develop and retain skilled employees and consultants in our business. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in our field is intense. Due to this intense competition, we may be unable to

continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. Any delay in replacing such persons, or an inability to replace them with persons of similar expertise, would have a material adverse effect on our business, financial condition and results of operations. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could subject us to significant liability and harm our reputation. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with regulations of domestic or foreign regulatory authorities. In addition, misconduct by employees could include intentional failures to comply with certain development standards, to report financial information or data accurately, or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. While prohibited, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. **Our internal computer systems, or those of our contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Despite the implementation of cyber security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For example, the loss of preclinical data or data from any future clinical trial involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed. Our** insurance may be insufficient to cover losses that may occur as a result of our operations. We currently maintain directors' and officers' liability insurance, clinical trial insurance and property and general liability insurance and intend in the future to obtain shipping and storage insurance for Product Candidates. This insurance may not remain available to us or be obtainable by us at commercially reasonable rates, and the amount of our coverage may not be adequate to cover any liability we incur. Future increases in insurance costs, coupled with the increase in deductibles, will result in higher operating costs and increased risk. If we were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if we were to incur such liability at a time when we were not able to obtain liability insurance, our business, results of operations and financial condition could be materially adversely affected. **Our insurance costs may increase significantly, we may be unable to obtain the same level of insurance coverage and our insurance coverage may not be adequate to cover all possible losses we may suffer. We generally renew our insurance policies annually. If the cost of coverage becomes too high or if we believe certain coverage becomes inapplicable, we may need to reduce our policy limits, increase retention amounts or agree to certain exclusions from our coverage to reduce the premiums to an acceptable amount or to otherwise reduce coverage for certain occurrences. On the other hand, we may determine that we either do not have certain coverage that would be prudent for our business and the risks associated with our business or that our current coverages are too low to adequately cover such risks. In either event, we may incur additional or higher premiums for such coverage than in prior years. Among other factors, national security concerns, catastrophic events, pandemics such as the COVID- 19 pandemic, or any changes in any applicable statutory requirement binding insurance carriers to offer certain types of coverage could also adversely affect available insurance coverage and result in, among other things, increased premiums on available coverage (which may cause us to elect to reduce our policy limits or not renew our coverage) and additional exclusions from coverage. As cyber incidents and threats continue to evolve, we may be required to expend additional, perhaps significant, resources to continue to update, modify or enhance our protective measures or to investigate and remediate any vulnerability to cyber incidents. Although we maintain and monitor our information technology systems and maintain coverage to indemnify us from losses arising from cyber- attacks, such systems and insurance coverage may not be sufficient to protect against or cover all the losses we may experience as a result of any cyberattacks. We may suffer damage due to a casualty loss (such as fire, natural disasters, pandemics and acts of war or terrorism) or other losses, such as those related to labor, professional liability or certain actions or inactions by our management, directors, employees or others, that could severely disrupt its business or subject us to claims by third parties who are injured or harmed. Although we maintain insurance that we believe to be adequate, such insurance may be inadequate or unavailable to cover all the risks to which our business and assets may be exposed, including risks related to certain litigation. Should an uninsured loss (including a loss that is less than the applicable deductible or that is not covered by insurance) or loss in excess of insured limits occur, it could have a significant adverse impact on our business, results of operations or financial condition.** There may be changes in laws, regulations and guidelines which are **material and** detrimental to our business. Our operations are subject to a variety of laws, regulations and guidelines relating to pharmacology, cannabinoids and drug delivery, as well as laws and regulations relating to health and safety, the conduct of operations, and the protection of the environment. While, to the knowledge of our management, we are currently in compliance with all such laws, changes to such laws, regulations and guidelines due to matters beyond our control may cause adverse effects to our operations and financial condition. These changes may require us to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan. In addition, if the governments of Canada or the United States were to enact or amend laws relating to our industry, it may decrease the size of, or eliminate entirely, the market for our Product Candidates, may introduce significant new competition into the market and may otherwise

potentially materially and adversely affect our business, results of operations and financial condition. If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected. The research and development that we carry out either directly or through third parties involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes. Although we maintain workers' compensation insurance as prescribed by the Province of British Columbia to cover us for costs and expenses, we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations. Our proprietary information, or that of our customers, suppliers and business partners, may be lost or we may suffer security breaches. In the ordinary course of our business, we may collect and store sensitive data, including intellectual property, data from preclinical studies, clinical trial data, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers, clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although to our knowledge we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disrupt our operations, damage to our ability to obtain patent protection for our Product Candidates, damage to our reputation, and cause a loss of confidence in our products and our ability to conduct clinical trials, which could adversely affect our business and reputation and lead to delays in gaining regulatory approvals. We expect to face intense competition, often from companies with greater resources and experience than we have. The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we have. Some of these competitors and potential competitors have more experience than we have in the development of pharmaceutical products, including validation procedures and regulatory matters. Other companies researching in the same disease areas may develop products that are competitive or superior to our Product Candidates. Other companies working in cannabinoid research may develop products targeting the same diseases that we are focused on that are competitive or superior to our Product Candidates. In addition, there are non-FDA approved Cannabis / cannabinoid preparations being made available from companies in the so-called "medical marijuana" industry, which may be competitive to our products. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed. **Industry consolidation may lead to increased competition and costs, and may harm our operating results. We rely on certain third parties to provide supplies and services necessary for our business. Any reduction in market participants and available suppliers and vendors, whether through transactions or consolidation, could result in fewer alternatives for sourcing key supplies and services. Such consolidation could result in a shortage of supplies and services thereby increasing the cost of such supplies and services, and potentially inhibit the ability of suppliers and vendors to deliver on time, if at all. Cost increases and delays in, or the unavailability of, critical supplies and services could have a material and adverse effect on our results of operations.** If we receive regulatory approvals, we intend to market our Product Candidates in multiple jurisdictions where we have limited or no operating experience and may be subject to increased business and economic risks that could affect our financial results. If we receive regulatory approvals, we may plan to market our Product Candidates in jurisdictions where we have limited or no experience in marketing, developing and distributing our products. Certain markets have substantial legal and regulatory complexities that we may not have experience navigating. We are subject to a variety of risks inherent in doing business internationally, including risks related to the legal and regulatory environment in non-U.S. jurisdictions, including with respect to privacy and data security, trade control laws and unexpected changes in laws, regulatory requirements and enforcement, as well as risks related to fluctuations in currency exchange rates and political, social and economic instability in foreign countries. If we are unable to manage our international operations successfully, our financial results could be adversely affected. Controlled substance legislation may differ in other jurisdictions and could restrict our ability to market our products internationally, which would result in increased business and economic risks that could affect our financial results. Controlled substance legislation may differ in other jurisdictions and could restrict our ability to market our products internationally. Most countries are parties to the Single Convention on Narcotic Drugs 1954, which governs international trade and domestic control of narcotic substances, including Cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining marketing approval for Product Candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our Product Candidates to be marketed or achieving such amendments to the laws and regulations may take a prolonged period of time. We would be unable to market our Product Candidates in countries with such obstacles in the near future or perhaps at all without modification to laws and regulations. Product liability lawsuits against us could cause us to incur substantial liabilities. Our use of our Product Candidates in clinical trials and the sale of our Product Candidates, if approved, exposes us to the risk of product liability claims. Product liability

claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our Product Candidates. For example, we may be sued if any product we develop allegedly causes injury or is alleged to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under local jurisdiction consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things: ● withdrawal of patients from our clinical trials; ● substantial monetary awards to patients or other claimants; ● decreased demand for our Product Candidates following marketing approval, if obtained; ● damage to our reputation and exposure to adverse publicity; ● increased FDA warnings on product labels or increased warnings imposed by the EMA or other regulatory authorities; ● litigation costs; ● distraction of management's attention from our primary business; ● loss of revenue; and ● the inability to successfully commercialize our Product Candidates, if approved. Our current clinical trial liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our Product Candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our share price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, results of operations, business and prospects could be materially adversely affected. Failure to protect our information technology infrastructure against cyber- based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. We rely on information technology, telephone networks and systems, including the internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities. We use enterprise information technology systems to record, process and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal and tax requirements. Despite the implementation of security measures, our information technology systems, and those of our third- party contractors and consultants, are vulnerable to a cyber- attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks could result in the theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber- attacks are becoming more sophisticated and frequent, and our systems could be the target of malware and other cyber- attacks. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. Nonetheless, our computer systems are subject to penetration and our data protection measures may not prevent unauthorized access. We can give no assurances that these measures and efforts will prevent interruptions or breakdowns. If we are unable to detect or prevent a security breach or cyber- attack or other disruption from occurring, then we could incur losses or damage to our data, or inappropriate disclosure of our confidential information or that of others; and we could sustain damage to our reputation, suffer disruptions to our research and development and incur increased operating costs including increased cybersecurity and other insurance premiums, costs to mitigate any damage caused and protect against future damage, and be exposed to additional regulatory scrutiny or penalties and to civil litigation and possible financial liability. For instance, the loss of preclinical or clinical data could result in delays in our development and regulatory filing efforts and significantly increase our costs.

**Certain macroeconomic and geopolitical conditions, which are outside of our control, as well as the evolution of methods and techniques used by bad actors, may also make us more susceptible to a cybersecurity attack. For example, tensions between Russia and several western nations (and their respective allies) in connection with the Russia- Ukraine War could result in retaliatory actions being undertaken by supporters of Russia, including in the form of espionage, phishing campaigns and other forms of cyber- attacks. Moreover, pro- Russian ransomware cybercriminals and gangs have previously publicly threatened to augment their hacking efforts in response to the implementation of sanctions and other responsive actions taken by western countries (and their allies). Increasing costs associated with information security, such as increased investment in technology, the cost of compliance and costs resulting from consumer fraud could cause our business and results of operations to suffer materially. Likewise, within a few hours of the commencement of the Hamas- Israel conflict, activist hackers commenced cyberattacks against both Israeli and Palestinian websites, and in a short period, had targeted dozens of government websites and media outlets. Such cyber- intrusions included DDOS attacks, attempts to overload websites with ' junk' traffic and ultimately bring down the site. The methods and techniques used by cyber threat actors to gain entry into our network and access our computer systems, software and data will become more advanced with the use of AI and may become increasingly difficult or impossible to detect and prevent. As these threats continue to evolve, we may be required to invest significant additional resources to modify and enhance our information security and controls or to investigate and remediate any security vulnerabilities. While our technology infrastructure is designed to safeguard and protect personal and business information, we have limited ability to monitor the implementation of similar safeguards by our vendors. Any cyberattack, unauthorized intrusion, malicious software infiltration, network disruption, corruption of data, misuse or theft of private or other sensitive information, or inadvertent acts by our own employees, could result in the disclosure or misuse of confidential or proprietary information, which could have a**

material adverse effect on our business operations or that of our clients. If we experience a significant data security breach, fail to detect and appropriately respond to a significant data security breach, or fail to comply with the various cybersecurity regulations, including the California Consumer Privacy Act and the California Privacy Rights Act in the United States, we could be exposed to government enforcement actions and private litigation. These losses may exceed our insurance coverage for such incidents. In addition, our employees and clients could lose confidence in our ability to protect their personal and proprietary information, which could cause them to terminate their relationships with us. Any loss of confidence arising from a significant data security breach could hurt our reputation, further damaging our business. Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. We are subject to various domestic and international data protection laws and regulations (i. e., laws and regulations that address privacy and data security). The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous laws, including data breach notification laws, health information privacy laws and consumer protection laws, govern the collection, use and disclosure of health- related and other personal information. In addition, we may obtain health information from third parties (e. g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA regulations. EU Member States, Australia and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. For example, the collection and use of personal data in the EU is governed by the provisions of the General Data Protection Regulation (or “GDPR”). The GDPR and the national implementing legislation of the EU Member States impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the rights of individuals to control personal data and the security and confidentiality of the personal data. The related UK GDPR and the UK Data Protection Act of 2018, which ensures that the United Kingdom has in effect the same high standards for data protection in place as under the GDPR, impose stringent operational requirements in the United Kingdom (including through restrictions on processing of personal data and cross- border transfers of personal data, and mandatory breach reporting to regulators and, under certain circumstances, to the individuals whose personal data was compromised in the breach). In addition, the Australian Privacy Act 1988 (Cth), and other laws in the states and territories in Australia where we conduct certain of our clinical trials, apply similar restrictions on our ability to collect, analyze and transfer medical records and other patient data. Other new laws and regulations are rapidly coming into effect while existing legislation is quickly evolving. In the United States, the SEC adopted new rules requiring public companies to disclose information about a material cybersecurity incident, including any breach of personal data, within four business days of determining that it has experienced a material cybersecurity incident. Likewise, several privacy laws in the United States came into effect in 2023, including in California, Virginia, Colorado, Connecticut and Utah, and new state privacy laws that have or will come into effect in 2024, including in Montana, Oregon and Texas, all of which give new data privacy rights to their respective residents and impose significant obligations on controllers and processors of consumer data. There is additionally increasing U. S. and foreign activity in the regulation of AI, and other similar uses of technology. For example, in Europe, there is a proposed regulation (the Artificial Intelligence Act) that, if adopted and approved, could impose onerous and substantial obligations related to the use of AI- related systems. Additionally, several states and localities in the United States have enacted measures related to the use of AI and machine learning in products and services. In October 2023, the President of the United States issued an executive order on the Safe, Secure and Trustworthy Development and Use of AI, emphasizing the need for transparency, accountability and fairness in the development and use of AI tools, and AI is the subject of evolving review by various governmental and regulatory agencies, including the SEC and the Federal Trade Commission. Depending on how these AI laws and regulations are interpreted, and to the extent that our business practices, products and services utilize AI, we could be subject to, and need to comply with, such obligations. Moreover, our development and use of AI, and the uncertain regulatory environment, could result in reputational harm, liability or other material and adverse consequences to our financial condition and business operations. The introduction of AI technologies into new or existing products may also result in new or enhanced governmental or regulatory scrutiny, litigation, confidentiality or security risks, ethical concerns, or other complications that could adversely affect our business, reputation, or financial results. The intellectual property ownership and license rights, including copyright, surrounding AI technologies has not been fully addressed by courts or national or local laws or regulations, and the use or adoption of third- party AI technologies into our products and services may result in exposure to claims of copyright infringement or other intellectual property misappropriation. Uncertainty around new and emerging AI technologies, such as generative AI, may require additional investment in the development and maintenance of proprietary datasets and machine learning models, development of new approaches and processes to provide attribution or remuneration to creators of training data, and development of appropriate protections and safeguards for handling the use of customer data with AI technologies, which may be costly and could impact our expenses if we decide to expand generative AI into our product offerings. AI technologies, including generative AI, may create content that appears correct but is factually inaccurate or flawed. Our customers or others may rely on or use this flawed content to their detriment, which may expose us to brand or reputational harm, competitive harm, and / or legal liability. The use of AI technologies presents emerging ethical and social issues, and if we enable or offer solutions that draw scrutiny or controversy due to their perceived or actual impact on customers or on society as a whole, we may experience brand or reputational harm, competitive harm, and / or legal liability. Existing privacy- related laws and regulations in the United States and other countries are evolving and are subject to potentially differing interpretations, and various U. S. federal and state or other international legislative and regulatory bodies may

expand or enact laws regarding privacy and data security- related matters. Due to the fact that privacy and information security laws and regulations are subject to change from time to time, our compliance with them may result in cost increases due to necessary systems changes and the development of new processes. Any new or modified laws and regulations may require that we modify our data processing practices and policies, and incur substantial costs and expenses in an effort to comply with such laws and regulations. These laws are complex and there is no ubiquitous approach to maintaining compliance. Requirements may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another or may conflict with other rules or our practices. If we fail to comply with any of these laws and regulations, we could be subjected to legal risk and other adverse effects to our business and operations. A claim or series of claims brought against us alleging a failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results and could cause our share price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, results of operations, business and prospects could be materially adversely affected. ~~The~~ Our results of operations could be materially and adversely affected if we cannot keep pace with technological changes impacting the development of our products and implementation of our business needs, including with respect to automation and the use of AI. Our success depends on our ability to keep pace with rapid technological changes affecting the development of our products and implementation of our business needs. Emerging technological trends such as AI, machine learning and automation are impacting industries and business operations. If we do not sufficiently invest in new technology and industry developments, appropriately implement new technologies or evolve our business at sufficient speed and scale in response to such developments, or if we do not make the right strategic investments to respond to these developments, our products, results of operations and ability to develop and maintain our business could be negatively affected. Our competitors or other third parties may incorporate AI technologies into their services, products and business more quickly or more successfully than us, which could impair our ability to compete effectively and materially and adversely affect our results of operations and financial condition. Growing emphasis by the investment community, regulators and other stakeholders on environmental, social and governance- related matters could impact our business and operations. As members of the investment community have started to heavily factor in a company' s commitment to environmental, social and governance (“ ESG ”)- related initiatives and sustainability performance as part of their overall investment thesis and strategy, such investors could elect to eventually forego their investment in us to the extent we fail to satisfy such metrics. Moreover, the increased focus by investors, regulators and other stakeholders on ESG related practices and disclosures has created, and will likely create for the foreseeable future, increased pressure regarding the enhancement of, and modification to, our disclosure and governance practices. Recently, there has been a growing concern and emphasis by governmental agencies regarding the effects of climate change on the environment and the need to make disclosures to investors regarding a company' s environmental footprint. For example, on March 6, 2024, the SEC adopted a final rule requiring public companies to include certain climate- related disclosures in their respective registration statements and annual reports filed with the SEC, including climate- related financial statement metrics, greenhouse gas emissions and climate- related targets and goals, and management' s role in managing material climate- related risks. A number of state legislators and regulators, including California laws S. B. 253, S. B. 261 and A. B. 1305 in the State of California, as well as non- U. S. governmental agencies (such as the EU' s Corporate Sustainability Reporting Directive), have adopted or are currently considering proposing or adopting other rules, regulations, directives, initiatives and laws requiring ESG- related disclosures or limiting (or affirmatively requiring) certain ESG- related conduct. In the event that we were to become subject to any of the newly adopted climate change and / or ESG- related disclosure regimes, including in the United States and elsewhere, it could require us to, among other things, (i) restrict or limit our operating activities or other conduct, (ii) make material capital improvements and expend material capital resources in connection with such compliance efforts, and (iii) alter our business and operational strategy more generally. Furthermore, there continues to be a lack of consistent proposed climate change and ESG- related legislation, which creates regulatory and economic uncertainty. Separately, enhanced climate- related disclosure requirements and obligations could lead to reputational or other harm with customers, regulators, investors or other stakeholders and could also increase our litigation risks relating to statements alleged to have been made by us or others in our industry regarding climate change risks, or in connection with any future disclosures we may make regarding reported emissions, particularly given the inherent approximations, estimations and uncertainties with respect to calculating, determining and reporting greenhouse gas emissions. Additionally, governmental regulators, including the SEC, have also from time to time applied additional scrutiny to existing climate change- related assertions in public disclosures, increasing the potential for enforcement if any such governmental regulator were to allege that our climate change- related disclosures are misleading or deficient. As a result of the foregoing, we currently face, and are likely to continue to face, increasing pressure regarding our ESG- related disclosures, practices, initiatives and sustainability performance in the near- and long- term. We continue to monitor for these changes and their potential impact on our business, financial condition and industry at large, and seek to implement measures to comply with all such newly implemented requirements; however, given the rapidly changing nature of these rules, regulations, directives, initiatives and laws, and the heightened regulatory scrutiny being applied by governmental agencies across numerous jurisdictions, it is not possible to predict how such matters will ultimately impact our business or that of our critical counterparties at this time. Climate change may have an impact on our business. While we seek to mitigate our business- related risks associated with climate change, we recognize that there are inherent climate- related risks wherever business is conducted. Any of our locations may be vulnerable to the adverse effects of climate change. Furthermore, it is more difficult to mitigate the impact of these events on our employees while

they work from home as a result of the COVID-19 coronavirus pandemic. Changing market dynamics, global policy developments, and the increasing frequency and impact of extreme weather events on critical infrastructure in the United States, Canada and elsewhere have the potential to disrupt our business, the business of our suppliers, and the business of our customers, and may cause us to experience higher attrition, losses and additional costs to maintain or resume operations. In particular, we rely on data centers to deliver our solutions, which consume significant amounts of energy. To the extent that energy prices increase as a result of carbon pricing or other measures, this could affect our cost structure. Our success depends on our ability to continue to innovate and create new products and enhancements to our existing products. To keep pace with technological developments, satisfy increasingly sophisticated customer requirements and achieve market acceptance, we must enhance and improve existing products and continue to introduce new products and services. If we are unable to successfully develop new products, integrate acquired products or enhance and improve existing products or if we fail to position and / or price our products to meet market demand, our business and operating results will be adversely affected. Accelerated product introductions and short product life cycles require high levels of expenditures for research and development that could adversely impact affect our results of operations. Further, the introduction of new products could require long development and testing periods and may not be introduced in a timely manner our- or business may not achieve the broad market acceptance necessary to generate significant revenue. Further, including several key activities that if a competitor develops a new, less expensive product using a different technological approach to delivering informational services over existing networks, our products would no longer be competitive. Conversely, even if we are critical to our success successful. The global outbreak in rapidly developing new products ahead of COVID-19 our competitors, if we do not cost -19 continues effectively manage our inventory levels of existing products when making the transition to rapidly evolve. As new products, our financial results could be negatively affected by write-offs as a result of, businesses have closed and limits have been placed on travel. The extent to which COVID-19 may impact our business will depend on future developments, which are highly- high levels uncertain and cannot be predicted with confidence, such as the ultimate impact of obsolete inventory the disease on specific geographies, the duration of the outbreak, travel restrictions and social distancing in the United States, Canada and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, Canada and other countries to contain and treat the disease. If any The spread of COVID-19 throughout the world has also created global economic uncertainty, which may cause partners, suppliers and potential customers to closely monitor their costs and reduce their spending budget. Any of the foregoing were to could materially adversely affect our occur research and development activities, our clinical trials, supply chain, financial condition and cash flows. If the COVID-19 outbreak continues to spread, we may need to limit operations- operating results or implement other limitations on our activities. There is a risk that countries or regions outside the United States and Canada may be less effective at vaccinations and containing COVID-19, in which case the risks described herein could be elevated significantly materially and adversely impacted. Risks Related to our Securities The market prices for our common Common shares Shares are volatile and will fluctuate. The trading price of our Common Shares has been and could remain volatile, and the market price of our Common Shares may decrease. The market price of our Common Shares has historically experienced and may continue to experience significant volatility. From July 1, 2023 through June 30, 2024, the closing market price of our Common Shares has fluctuated from a high of \$ 1.22 per share to a low of \$ 0.22 per share. The volatile nature of our Common Share price may cause investment losses for our stockholders. In addition, the market price of stock in small capitalization biotech companies is often driven by investor sentiment, expectation, and perception, all of which may be independent of fundamental, objective, and intrinsic valuation metrics or traditional financial performance metrics, thereby exacerbating volatility. The market price for our common Common shares Shares may be anticipated to be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond our control, including the following: (i) actual or anticipated fluctuations in our quarterly financial results; (ii) recommendations by securities research analysts; (iii) changes in the economic performance or market valuations of other issuers that investors deem comparable to ours; (iv) addition or departure of our executive officers or members of our Board and other key personnel; (v) release or expiration of lock-up or other transfer restrictions on outstanding common Common shares Shares; (vi) sales or perceived sales of additional common Common shares Shares; (vii) liquidity of the common Common shares Shares; (viii) significant acquisitions or business combinations, strategic partnerships, joint ventures or capital commitments by or involving us or our competitors; and (ix) news reports relating to trends, concerns, technological or competitive developments, regulatory changes and other related issues in our industry or target markets. Financial markets often experience significant price and volume fluctuations that affect the market prices of equity securities of public entities and that are, in many cases, unrelated to the operating performance, underlying asset values or prospects of such entities. Accordingly, the market price of our common Common shares Shares may decline even if our operating results, underlying asset values or prospects have not changed. Additionally, these factors, as well as other related factors, may cause decreases in asset values that are deemed to be other than temporary, which may result in impairment losses. As well, certain institutional investors may base their investment decisions on consideration of our environmental, governance and social practices and performance against such institutions' respective investment guidelines and criteria, and failure to meet such criteria may result in limited or no investment in our common Common shares Shares by those institutions, which could materially adversely affect the trading price of our common Common shares Shares. There can be no assurance that continuing fluctuations in price and volume will not occur. If such increased levels of volatility and market turmoil continue for a protracted period of time, our operations could be materially adversely impacted and the trading price of our common Common shares Shares may be materially adversely affected. Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or Product Candidates. We will seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing

arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our Product Candidates or grant licenses on terms that are not favorable to us. Future offerings of debt or equity securities may rank senior to ~~our common Common shares Shares~~. If we decide to issue debt or equity securities in the future ranking senior to ~~common Common shares Shares~~ or otherwise incur additional indebtedness, it is possible that these securities or indebtedness will be governed by an indenture or other instrument containing covenants restricting our operating flexibility and limiting our ability to pay dividends to shareholders. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences and privileges, including with respect to dividends, more favorable than those of ~~common Common shares Shares~~ and may result in dilution to shareholders. Because our decision to issue debt or equity securities in any future offering or otherwise incur indebtedness will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or financings, any of which could reduce the market price of our ~~common Common shares Shares~~ and dilute their value. **More generally, our level of indebtedness could have significant and adverse effects on our business. For example, our level of indebtedness and the terms of our debt agreements could: (i) make it more difficult for us to satisfy our financial obligations under our indebtedness and our contractual and commercial commitments and increase the risk that we may default on our debt obligations; (ii) prevent us from raising the funds necessary to repurchase notes tendered to us if we undergo a change of control; (iii) require us to use a substantial portion of our cash flow from operations to pay interest and principal on the Second Amended and Restated Credit Agreement and other debt, which would reduce the funds available for working capital, capital expenditures and other general corporate purposes; (iv) limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments, or general corporate purposes, which may limit our ability to execute our business strategy; (v) limit our ability to refinance our current or future indebtedness on terms that are commercially reasonable, if at all; (vi) heighten our vulnerability to downturns in our business, our industry or in the general economy, and restrict us from exploiting business opportunities or making acquisitions; (vii) place us at a competitive disadvantage compared to those of our competitors that may have proportionately less debt; (viii) limit management's discretion in operating our business; and (ix) limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy. Each of these factors may have a material and adverse effect on our financial condition and viability. Our ability to satisfy our other debt obligations will depend on our future operating performance, which will be affected by prevailing economic conditions and financial, business and other factors affecting our company and industry, many of which are beyond our control.** Future sales of ~~common Common shares Shares~~ by our officers and, directors and affiliates may negatively impact the market price for our ~~common Common shares Shares~~. Subject to compliance with applicable securities laws, our directors and officers and their affiliates may sell some or all of their ~~common Common shares Shares~~ in the future. No prediction can be made as to the effect, if any, such future sales of ~~common Common shares Shares~~ may have on the market price of the ~~common Common shares Shares~~ prevailing from time to time. However, the future sale of a substantial number of ~~common Common shares Shares~~ by our directors and officers and their affiliates, or the perception that such sales could occur, could adversely affect prevailing market prices for our ~~common Common shares Shares~~. We do not currently pay dividends on our ~~common Common shares Shares~~ and have no intention to pay dividends on our ~~common Common shares Shares~~ for the foreseeable future. No dividends on our ~~common Common shares Shares~~ have been paid by us to date. We do not intend to declare or pay any cash dividends in the foreseeable future. Payment of any future dividends will be at the discretion of our Board, after taking into account a multitude of factors appropriate in the circumstances, including our operating results, financial condition and current and anticipated cash needs. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends unless certain consents are obtained and certain conditions are met. We are exposed to risks related to currency exchange rates. We currently hold ~~most the majority~~ of our cash, cash equivalents and short-term investments in U. S. dollars which is our functional currency. A portion of our current operations is conducted in Canadian dollars. Exchange rate fluctuations between other currencies and the U. S. dollar create risk in several ways, including the following: • weakening of the Canadian dollar may decrease the value of our Canadian dollar cash, cash equivalents and short-term investments; • weakening of the U. S. dollar may increase the cost of operations and products / services sourced in Canada; • the exchange rates on non- U. S. dollar transactions and cash deposits can distort our financial results; and • commercial product pricing and profit margins are affected by currency fluctuations. For as long as we are an "emerging growth company" we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our ~~common Common shares Shares~~ being less attractive to investors and could make it more difficult for us to raise capital as and when we need it. We are an "emerging growth company," as defined in the JOBS Act, and we have taken advantage, and intend to continue to take advantage, of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the

requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. Investors may find our ~~common~~ **Common shares Shares** less attractive because we rely on these exemptions, which could contribute to a less active trading market for our ~~common~~ **Common shares Shares** or volatility in our share price. In addition, we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. **There remains increased focus from lawmakers and regulators on corporate ESG practices, including climate change and related ESG disclosure requirements. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), changes in demand for certain products, enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition or results of operations. In addition, standards for tracking and reporting ESG matters continue to evolve, and our business may be impacted by new laws, regulations or investor criteria in the United States, Europe and around the world related to ESG. In March 2024, the SEC adopted new rules that will require registrants to provide certain climate-related information in their registration statements and annual reports. The rules require information about a registrant's climate-related risks that are reasonably likely to have a material impact on its business, results of operations, or financial condition. The required information about climate-related risks will also include disclosure of a registrant's greenhouse gas emissions. In addition, the rules will require registrants to present certain climate-related financial metrics in their audited financial statements. The SEC's newly adopted climate-related disclosure rules may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past and expanded data collection, analysis and certification with respect to greenhouse gas emissions reporting that may not be complete or accurate, and impose increased oversight obligations on our management and board of directors. These and other regulations, disclosure-related and otherwise, including California laws S. B. 253, S. B. 261 and A. B. 1305 and the EU's Corporate Sustainability Reporting Directive, may increase our costs as well as increase scrutiny regarding our ESG efforts, which may enhance the risks discussed in this risk factor. These legal and regulatory requirements, as well as investor expectations related to ESG practices and disclosures are subject to change, can be unpredictable, and may be difficult and expensive for us to comply with. If we fail to adapt to or comply with all laws, regulations, policies and related interpretations, our business and reputation could be negatively impacted, and our share price and access to / cost of capital could be materially and adversely affected. Additionally, many of our customers and suppliers may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us.** If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our ~~common~~ **Common shares Shares**. We will be required, under Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes- Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. This may expose us, including individual executives, to potential liability which could significantly affect our business. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting once that firm begins its audits of internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ~~common~~ **Common shares Shares** could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the

realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. Deficiencies in disclosure controls and procedures and internal control over financial reporting could result in a material misstatement in our financial statements. We could be adversely affected if there are deficiencies in our disclosure controls and procedures or in our internal controls over financial reporting. The design and effectiveness of our disclosure controls and procedures and our internal controls over financial reporting may not prevent all errors, misstatements or misrepresentations. Consistent with other entities in similar stages of development, we have a limited number of employees currently in the accounting group, limiting our ability to provide for segregation of duties and secondary review. A lack of resources in the accounting group could lead to material misstatements resulting from undetected errors occurring from an individual performing primarily all areas of accounting with limited secondary review. Deficiencies in internal controls over financial reporting which may occur could result in material misstatements of our results of operations, restatements of financial statements, other required remediations, a decline in the price of our ~~common~~ **Common Shares**, or otherwise materially adversely affect our business, reputation, results of operations, financial condition or liquidity. In connection with the audit of our financial statements as of and for the ~~years-~~ **year** ended June 30, 2023 ~~and 2022~~, a ~~material weaknesses-~~ **weaknesse** in our internal control over financial reporting ~~were was~~ identified and we may identify additional material weaknesses in the future. In connection with the preparation and audits of our financial statements as of and for the ~~years-~~ **year** ended June 30, 2023 ~~and 2022~~, a material weakness, (as defined under the Exchange Act and by the auditing standards of the U. S. Public Company Accounting Oversight Board (~~,~~ or “PCAOB”)), was identified in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual financial statements will not be prevented or detected on a timely basis. The identified control deficiencies arose from a lack of resources in our finance function, which rose to a material weakness due to segregation of duty issues. In light of the identified material weakness, it is possible that, had we performed a formal assessment of our internal control over financial reporting or had our independent registered public accounting firm performed an audit of our internal control over financial reporting in accordance with PCAOB standards, additional control deficiencies may have been identified. We ~~subsequently designed have begun taking measures, and implemented controls plan to continue to take measures,~~ to remediate ~~this the~~ material weakness ~~;~~ **However, including strengthening our finance function and the implementation of these measures may not fully address addressing this segregation of duty issues. While our management has determined that we have remediated such** material weakness ~~in as of our fiscal year ended June 30, 2024, we cannot assure you that (i) the measures we have taken our- or will take will be entirely sufficient to remediate the material weakness or avoid the identification of additional material weaknesses in the future nor (ii) we will not experience flaws in our internal controls and procedures in the future. Our failure to implement and maintain effective~~ internal control over financial reporting ~~;~~ and, if so, we would not be able to conclude that they have been fully remedied. Our failure to correct this material weakness or our failure to discover and address any other control deficiencies could result in ~~inaccuracies the identification of additional errors~~ in our **consolidated** financial statements ~~and that could also impair result in a further restatement of our ability to comply with applicable financial statements and could cause us to fail to meet our periodic reporting requirements obligations, any of which could diminish investor confidence in us, cause a decline in the price of our Common Shares and make related subject us to litigation or regulatory enforcement actions~~ filings on a timely basis. As a result, our business, financial condition, results of operations and prospects, as well as the trading price of our common shares, may be materially and adversely affected. We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management has been required, and will continue to be required, to devote substantial time to new compliance initiatives. As a public company, we have incurred and are continuing to incur significant legal, accounting and other expenses and these expenses may increase even more after we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Exchange Act and the rules adopted, and to be adopted, by the SEC. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. The increased costs have increased our net loss. These rules and regulations may make it more difficult and more expensive for us to maintain sufficient director’s and officer’s liability insurance coverage. We cannot predict or estimate the amount or timing of additional costs we may continue to incur to respond to these requirements. The ongoing impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers. Future sales and issuances of our ~~common~~ **Common Shares** or rights to purchase ~~common~~ **Common Shares** pursuant to our equity incentive plan could result in additional dilution of the percentage ownership of our shareholders and may cause our share price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of ~~common~~ **Common Shares** or securities convertible into or exchangeable for ~~common~~ **Common Shares**. These future issuances of ~~common~~ **Common Shares** or ~~common~~ **Common Share**-related securities to purchase ~~common~~ **Common Shares**, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to those of holders of our ~~common~~ **Common Shares**. Pursuant to our 2017 Amended and Restated Stock Option Plan, and as amended at our Annual General Meeting in November 2020, our compensation committee is authorized to grant equity-based incentive awards in the form of options to purchase common shares to our directors, executive officers and other employees and service providers. As of September 20, 2023 ~~2024~~, there were ~~51-179~~, ~~633-293~~ options available for future

allocation pursuant to the 20 % of the issued and outstanding shares allowed to be issued according to the terms of the Plan. Future equity incentive grants under our stock option plan may result in material dilution to our shareholders and may have an adverse effect on the market price of our common shares. Provisions in our corporate charter documents and certain Canadian laws could delay or deter a change of control. Provisions in our articles and our by-laws, as well as certain provisions under the BCBCA and applicable Canadian securities laws, may discourage, delay or prevent a merger, acquisition, tender offer or other change in control of us that some shareholders may consider favorable. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board. As well, our preferred shares are available for issuance from time to time at the discretion of our Board, without shareholder approval. Our articles allow our Board, without shareholder approval, to determine the special rights to be attached to our preferred shares, and such rights may be superior to those of our ~~common~~ **Common Shares**. In addition, limitations on the ability to acquire and hold our ~~common~~ **Common Shares** may be imposed by the Competition Act in Canada. This legislation permits the Commissioner of Competition of Canada ~~or (the~~ **“ Commissioner ”** ~~)~~, to review any acquisition of a significant interest in us. This legislation grants the Commissioner jurisdiction to challenge such an acquisition before the Canadian Competition Tribunal if the Commissioner believes that it would, or would be likely to, result in a substantial lessening or prevention of competition in any market in Canada. The Investment Canada Act subjects an acquisition of control of a company by a non-Canadian to government review if the value of our assets, as calculated pursuant to the legislation, exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to result in a net benefit to Canada. Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities for our shareholders to sell their shares. If securities or industry analysts publish inaccurate or unfavorable research about our business, our share price and trading volume may decline. The trading market for our ~~common~~ **Common Shares** depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our shares or publish inaccurate or unfavorable research about our business, our share price may decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our shares may decrease, which may cause our share price and trading volume to decline. We are incorporated in Canada, with our assets and officers primarily located in Canada, with the result that it may be difficult for investors to enforce judgments obtained against us or some of our officers. We are a company organized and existing under the laws of British Columbia, Canada. Many of our directors and officers and the experts named in this Annual ~~Report Form on 10-K~~ **Report Form on 10-K** are residents of Canada or otherwise reside outside the United States, and all or a substantial portion of their assets, and a substantial portion of our assets, are located outside the United States. It may be difficult for holders of ~~common~~ **Common shares Shares** who reside in the United States to effect service within the United States upon those directors, officers and experts who are not residents of the United States. It may also be difficult for holders of 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, officers and experts under the U. S. federal securities laws. Our Canadian counsel has advised us that there is doubt as to the enforceability in Canada against us or against our directors, officers and experts who are not residents of the United States, in original actions or in actions for enforcement of judgments of courts of the United States, of liabilities predicated solely upon U. S. federal or state securities laws. Conversely, some of our directors and officers reside outside Canada and some of our assets are also located outside Canada. Therefore, it may not be possible for you to enforce in Canada against our assets or those directors and officers residing outside Canada, judgments obtained in Canadian courts based upon the civil liability provisions of the Canadian securities laws or other laws of Canada. Risks Related to our Financial Position and Capital Needs Our operating losses have raised substantial doubt regarding our ability to continue as a going concern. Our operating losses raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the years ended June 30, ~~2023-2024~~ **2024** and June 30, ~~2022-2023~~ **2023** with respect to this uncertainty. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. Since our inception as a pharmaceutical company in October 2014, we have devoted substantially all of our resources to the development of our proprietary Product Candidates. We have generated significant operating losses since our inception with an accumulated deficit to June 30, ~~2023-2024~~ **2024** of approximately \$ ~~101-109.4~~ **109.4** million. Our ~~comprehensive net losses-- loss~~ **comprehensive net losses-- loss** for the fiscal years ended June 30, ~~2024 and 2023 was and 2022 were~~ **2024 and 2023 was and 2022 were** approximately \$ ~~7.7 million and \$ 8.0 million and \$ 18.6 million, respectively~~ **7.7 million and \$ 8.0 million and \$ 18.6 million, respectively**. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses will increase as we continue the research and development of, and clinical trials for, our Product Candidates. In addition to budgeted expenses, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If our Product Candidates fail in preclinical or clinical trials, or do not gain regulatory approval, or even if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Due to our limited operating history and history of losses, any predictions about our future success, performance or viability may not be accurate. We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our Product Candidates. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial and increasing amounts to conduct further research and development, preclinical testing and clinical trials of our Product Candidates, to seek regulatory

approvals and reimbursement for our Product Candidates and to launch and commercialize any Product Candidates for which we receive regulatory approval. As of June 30, 2023-2024, we had approximately \$ 9-6. 0-6 million in cash, cash equivalents and short- term investments, which, we currently estimate funds our operations into to the end second half of fiscal 2024, and possibly into the third fourth quarter of fiscal calendar 2024 (being the second calendar fiscal quarter of 2024 2025 ), depending on the level and timing of realizing revenues from the sale of BayMedica inventory as well as the level and timing of the Company' s operating expenses. Our ability to develop our research and development programs is subject to accessing additional capital, including through the sale of equity, partnership revenues, and out- licensing activities. There is no assurance that we will be successful in these efforts. The progress of our Product Candidates for both current and prospective target indication (s) is uncertain because it is difficult to predict our spending for our Product Candidates up to the time that we seek FDA approval due to numerous factors, including, without limitation, the rate of progress of clinical trials, the results of preclinical studies and clinical trials for such indication, the costs and timing of seeking and obtaining FDA and other regulatory approvals for clinical trials and FDA guidance regarding clinical trials for such indication. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. For these reasons, we are unable to state unequivocally the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our Product Candidates; • any change in the clinical development plans or target indications for these Product Candidates; • the number and characteristics of Product Candidates that we develop or may in- license; • the terms of any collaboration agreements we may choose to execute; • the outcome, timing and cost of meeting regulatory requirements established by the Drug Enforcement Administration (, or “ DEA ” ), the FDA, the European Medicines Agency, or “ EMA ”, Health Canada (, or “ HC ” ), or other comparable foreign regulatory authorities; • The cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; • the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us; • the effect of competing product and market developments; • the costs and timing of the implementation of commercial scale manufacturing activities; and • the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any Product Candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our Product Candidates or one or more of our other research and development initiatives. Any doubt about our ability to continue as a going concern may materially and adversely affect the price of our common Common shares Shares, and it may be more difficult for us to obtain financing. Any doubt about our ability to continue as a going concern may also adversely affect our relationships with current and future collaborators, contract manufacturers and investors, who may become concerned about our ability to meet our ongoing financial obligations. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our financial resources may be limited. We have prepared our financial statements on a going concern basis, which assumes that we will be able to meet our commitments, realize our assets and discharge our liabilities in the normal course of business. Our consolidated financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. We may have difficulties identifying, successfully completing or integrating acquisitions, or maintaining or growing our acquired businesses. We remain committed to our growth strategy of organically growing our strategic portions of our business while assessing strategic acquisitions, dispositions, partnerships and other strategic transactions. While we believe we have the experience required to execute this strategy, we do not have control over the market conditions prevailing or likely to prevail in the future, which may impact the ability to execute this strategy. There can be no assurances that we will be able to identify suitable acquisition candidates available for sale at reasonable valuations, consummate any acquisition or successfully integrate any acquired business into our operations. Moreover, there can be no assurance that we will be able to access further financial resources for other suitable acquisition opportunities that may become available to us. We have and will likely continue to have competition for acquisition opportunities from other parties including those that have greater financial resources or are willing to pay higher valuation multiples. To the extent we were to pursue or engage in any transactions, including acquisitions and dispositions, there is no guarantee that such transactions will be successful or, even if consummated, improve our operating results and financial condition. We may incur costs, breakage fees or other expenses in connection with any such transactions, and any such transactions may ultimately have a material adverse effect on our operating results. Acquisitions involve significant risks and uncertainties, including, but not limited to, the following: • unanticipated costs and liabilities; • difficulties in marketing and integrating new products, software, businesses, operations and technology infrastructure in an efficient, effective and secure manner, including the integration of businesses where a portion or all of the business is in an adjacent industry; • the inability to achieve synergy and cost reduction targets assumed at the time of acquisition; • difficulties in maintaining customer and key supplier relations, including changing contract manufacturers as a result of lower volumes of business; • the potential loss of key employees of the acquired businesses, including as a result of cultural differences between the acquired company and our own; • the diversion of the attention of our senior management from the operation of our daily business; • the potential adverse effect on our net debt and liquidity position as a result of all or a portion of an acquisition purchase price being paid in cash; • the potential significant increase of our interest expense, leverage and debt service requirements if we incur additional debt to pay for an acquisition; • the potential issuance of securities that would dilute our shareholders'

percentage ownership; • the potential to incur restructuring and other related expenses, including significant transaction costs that may be incurred regardless of whether a potential strategic acquisition or investment is completed; • use of resources that are needed in other areas of our business; • the inability to maintain uniform standards, controls, policies and procedures, including the inability to establish and maintain adequate internal controls over financial reporting, and remediate, in whole or in part, any material weaknesses or significant deficiencies identified with respect to internal controls over financial reporting; • difficulties in entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions; • difficulties in securing required regulatory approvals or otherwise satisfy closing conditions for a proposed transaction in a timely manner, or at all; • potential impairment charges on higher levels of goodwill and intangible assets as a result of impairment testing performed on a regular basis; • higher amortization expenses related to acquired definite-lived intangible assets; and • becoming subject to intellectual property or other litigation. We

currently have limited commercial revenue and may never become profitable. In addition to the limited revenues from our BayMedica Products, our ability to generate revenue and become profitable depends upon our ability to obtain regulatory approval for, and successfully commercialize, our Product Candidates that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these Product Candidates, we do not know what the reimbursement status of our Product Candidates will be or when any of these products will generate revenue for us, if at all. We have not generated, and do not expect to generate, any revenue from Product Candidates for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our Product Candidates. The amount-number of future losses is uncertain and will depend, in part, on the rate of growth of our expenses. Our ability to generate revenue and become profitable depends upon a number of additional factors, including our ability to: • successfully complete development activities, including the remaining preclinical studies and ongoing and planned clinical trials for our Product Candidates; • in-license or acquire in the future, Product Candidates and other potential lines of business that we may develop; • complete and submit NDAs to the FDA and Marketing Authorization Applications (, or “ MAAs ” ) to the EMA, and obtain regulatory approval for indications for which there is a commercial market; • complete and submit applications to, and obtain regulatory approval from, other foreign regulatory authorities; • manufacture any approved products in commercial quantities and on commercially reasonable terms; • develop a commercial organization, or find suitable partners, to market, sell and distribute approved products in the markets in which we have retained commercialization rights; • achieve acceptance among patients, clinicians and advocacy groups for any products we develop; • obtain coverage and adequate reimbursement from third parties, including government payors; and • set a commercially viable price for any products for which we may receive approval. We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the processes described above, we anticipate incurring significant costs associated with commercializing our Product Candidates. Changes in tax laws and unanticipated tax liabilities could adversely affect our effective income tax rate and ability to achieve profitability. We are subject to income taxes in the United States and Canada. As our operations expand, we may become subject to income tax in jurisdictions outside of the United States and Canada. Our effective income tax rate in the future could be adversely affected by a number of factors including changes in the mix of earnings (losses) in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws. We regularly assess all of these matters to determine the adequacy of our tax provision which is subject to discretion. If our assessments are incorrect, it could have an adverse effect on our business and financial condition. There can be no assurance that income tax laws and administrative policies with respect to the income tax consequences generally applicable to us or to our subsidiaries will not be changed in a manner which adversely affects our shareholders. Our ability to use our net operating loss carryforwards and other tax attributes may be materially limited. As of **June 30, 2024** our last fiscal year end, we had non-capital loss (, or “ NOL ” ), carry-forwards-carryforwards of approximately \$ **71-80.6-2** million available to offset future taxable income in Canada and the United States. These NOL carry-forwards begin to expire in 2026. Our NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under provisions in the Canadian Income Tax Act, and corresponding provisions of Canadian provincial law, if a corporation undergoes an “ ownership change, ” generally defined as a greater than 50 % change, by value, the corporation’s ability to use its pre-change Canadian NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. Specifically, NOLs from a business before the change of control may be carried forward to taxation years after the change of control, but only if the same business is carried forward on after the change in control with a reasonable expectation of profit, and only to offset income from that business or a similar business. We have not performed any analyses under the applicable provisions in the Canadian Income Tax Act and cannot forecast or otherwise determine our ability to derive benefit from our various federal or provincial tax attribute carryforwards. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset Canadian federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the provincial level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase provincial taxes owed. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our share ownership, including in any future offerings, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. Changes to accounting standards may adversely impact the manner in which we report our financial position and operating results. There are ongoing projects conducted by the Financial Accounting Standards Board in the United States that are expected to result in new pronouncements that continue to evolve, which could adversely impact the manner in which we report our financial position and operating results. **Global Economic Uncertainty** **Natural disasters, public health crises, political crises, or other catastrophic events may adversely affect our**

**business affairs, results of operations, financial condition, liquidity, availability of credit and foreign exchange exposure.**

Changes in the global economic environment have created market uncertainty and volatility in recent years. The market and demand for metal commodities and related products has in recent years been adversely affected by global economic uncertainty, reduced confidence in financial markets, the COVID- 19 pandemic, **including any resurgence thereof**, bank failures and credit availability concerns. These macro- economic events negatively affected the mining and minerals sectors in general. Global financial conditions remain subject to sudden and rapid destabilizations in response to economic shocks. A slowdown in the financial markets or other economic conditions, including but not limited to reduced consumer spending, decreased employment rates, adverse business conditions, high inflation, high fuel and energy costs, high consumer debt levels, a lack of available credit, the state of turmoil in the financial markets, high interest rates and / or tax rates, may adversely affect the Company' s growth and profitability. Future economic shocks may be precipitated by a number of causes, including the slowdown in the Chinese economy, a rise in the price of oil and other commodities, climate change disasters, geopolitical instability, **including as a direct or indirect result of the Russo- Ukraine war and the ongoing Israel- Hamas conflict**, further wars or acts of terrorism, the devaluation and volatility of global stock markets and natural disasters. Any sudden or rapid destabilization of global economic conditions could impact the Company' s ability to obtain equity or debt financing in the future on terms favorable to the Company or at all. In such an event, the Company' s operations and financial condition could be adversely impacted. The Company assesses on a quarterly basis the carrying values of its assets. Should market conditions and commodity prices worsen and persist in a worsened state for a prolonged period of time, an assessment of the Company' s assets for impairment may be required. **The ongoing Russo- Ukraine War and the Israel- Hamas conflict, including the actual or perceived threat of an exacerbation of such conflicts, could have a material and adverse effect on our business, operations and financial condition. Russia' s invasion of Ukraine in February 2022 has caused, and could continue to cause, increased volatility across the global financial markets, increased inflation, and turbulence in the markets in which we operate. In response to actions undertaken by Russia in Ukraine, several countries (including Canada, the United States and other western governments) have imposed stringent economic sanctions and export control measures, and may impose additional sanctions or export control measures in the near- term, which have included severe and complete restrictions on exports and other commerce and business dealings involving Russia, certain regions of Ukraine, Belarus and / or particular entities and individuals. In May 2023, in coordination with the G7, Australia, and other partners, the United States imposed new sanctions on Russia. As part of these actions, the U. S. Department of State imposed sanctions on over 200 entities, individuals, vessels, and aircraft, as well as designated certain entities and individuals (i) across Russia' s defense and related materiel, technology, and metals and mining sectors and (ii) involved in expanding Russia' s future energy production and capacity. In December 2023, President Biden signed an executive order which seeks to strengthen U. S. sanctions authorities against financial facilitators of Russia' s war efforts, and additionally provided authority to broaden U. S. import bans on certain Russian goods. Likewise, in February 2024, the United States' Treasury Department, State Department and Department of Commerce, collectively, imposed an extensive set of new sanctions on Russia, which specifically target Russia' s financial sector and military- industrial operations. Such sanctions seek to restrict Russia' s energy industry and limit the evasion of sanctions outside the United States, including by encompassing 500 additional persons associated with the ongoing Russo- Ukraine War. Moreover, the resulting impact of sanctions imposed by western nations against Russia, Russian- backed separatist regions in Ukraine, certain banks, companies, government officials, and other individuals in Russia and Belarus, could adversely impact our ability to access additional capital funding sources. Likewise, the recent and ongoing conflict in the Middle East has impacted and could continue to impact the global economy for the foreseeable future, and is threatening to spread, and may in the future spread, into other Middle Eastern countries. The conflicts have caused, and could intensify, volatility in market prices, and the extent and duration of the military actions, sanctions and resulting market disruptions could be significant and could potentially have a substantial negative impact geopolitical stability and on our business for an unknown period of time. In addition, any further changes in regulations or shifts in political conditions are beyond the control of the Company and may materially and adversely affect our business, or if significant enough, may significantly impede our ability to transact in certain countries. Operations may be affected in varying degrees by government regulations with respect to restrictions on production, price controls and foreign exchange restrictions. While we do not have any direct significant exposure or connection to Russia, Ukraine, Belarus or the Middle East at large, it is uncertain as to how such events and any related economic sanctions could impact the global economy. Any negative developments in respect thereof could have a material and adverse effect on our business, operations, financial condition, and the value of our securities. High rates of global inflation, the occurrence of a recession and higher interest rates could have a material and adverse impact on our business, results of operations and financial condition. During 2022 and 2023, the global markets experienced, and continue to experience, higher rates of inflation as a result of several market factors, including in the form of increased costs pertaining to labor, materials and overhead. The U. S. capital markets in particular have experienced and continue to experience extreme volatility and disruption. Inflation rates in the U. S. significantly increased in 2022 and 2023 resulting in action by the U. S. federal government to increase interest rates, adversely affecting capital markets activity. Interest rates are sensitive to factors that are beyond our control, including domestic and international economic conditions, including inflation, and the policies of various governmental and regulatory agencies, including the Federal Reserve Board in the United States (the " Federal Reserve "). Interest rates may increase further, or they may remain at current levels for the near- term, and this new interest rate environment could materially and adversely affect our business, the counterparties with which we interact and the global economy at large. As a result of these inflationary pressures, governments in many countries have implemented tight monetary policies, which could slow the growth rate of local economies and restrict the availability of credit. In**

particular, the monetary policies of the Federal Reserve, implemented through open market operations, the federal funds rate (“ Fed Funds Rate ”) targets, and the discount rate for banking borrowings and reserve requirements, affect prevailing interest rates. A material change in any of these policies could have a material impact on us or our customers, and therefore on our results of operations. Beginning early in 2022 and continuing in 2023, in response to growing indications of inflation, the Federal Reserve increased interest rates rapidly and the Fed Funds Rate reached a 23- year high in 2023. While we experienced increases in the cost of labor and materials, we believe that our financial condition and results of operations have thus far not been materially impacted by inflationary pressures. However, to the extent the current rates of inflation and shifts in fiscal and monetary policy result in prolonged and slower growth or a recession, it could have a material and adverse effect on the demand for our products and services and, in the process, our business, results of operations and financial condition as a whole, including with respect to our ability to maintain current levels of gross margin and general and administrative expenses as a percentage of total revenue. Moreover, in the event that a global recession were to occur, it could adversely impact the critical counterparties that we engage, including in the form of a decrease in the products and services they seek to obtain from us. Additionally, due to our current level of debt, our business and results of operations have been, and may continue to be, impacted by a rise in interest rates, which may continue to rise. Relatively high interest rates will increase cost of capital and the cost of borrowings for any other corporate purpose. As a result, if we need or seek significant borrowings and interest rates remain elevated or increase, the cost of such borrowing to us could be significant, which may have a significant adverse impact on our financial condition and results of operations. We continue to monitor our operations and will seek to take appropriate actions to mitigate the potential impact of heightened inflation on our business. Nevertheless, there can be no assurances that we will be successful in doing so, if at all. Material and adverse developments impacting the financial services industry at large, including the occurrence of actual (or widespread concerns regarding the potential occurrence of) defaults, illiquidity, operational failures and non- performance by financial institutions and critical counterparties, could have a material and adverse effect on our business, financial condition and results of operations. The occurrence of actual (or widespread concerns regarding the potential occurrence of) illiquidity, operational failures, defaults, non- performance or other material and adverse developments that impact financial institutions and transactional counterparties, or other entities within the financial services industry at large, have previously caused, and could continue to cause, market- wide liquidity issues, bank- runs and general contagion across the global financial industry. For example, on March 10, 2023, Silicon Valley Bank (“ SVB ”) was closed by the California Department of Financial Protection and Innovation and the Federal Deposit Insurance Corporation (the “ FDIC ”) was subsequently appointed as a receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each placed into receivership. While the U. S. Federal Reserve Board, the FDIC and the U. S. Department of Treasury collectively agreed to guarantee all deposits, above and beyond the limit on insured deposits of \$ 250, 000 at these financial institutions, there can be no assurance that there will not be additional bank failures or issues in the broader financial system. Likewise, there is no guarantee that any of the U. S. Department of Treasury, the FDIC or the Federal Reserve Board will provide access to any additional uninsured funds in the future in the event of the closure or failure of any other banks or financial institutions, or that they would do so promptly or in a timely fashion. Additionally, substantial and rapid increases in interest rates and inflation have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. While the U. S. Department of Treasury, Federal Reserve and the FDIC have announced a program to provide up to \$ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, the liquidity needs of financial institutions, including as a result of widespread demands for customer withdrawals, may exceed the capacity of such program. Furthermore, we and other parties with whom we conduct business and engage commercially may be unable to access critical funds in deposit accounts or other accounts held with a closed or failing financial institution or pursuant to lending arrangements with such financial institutions. Accordingly, in such instance, our ability to pay our obligations, and any of our counterparties’ ability to pay their respective obligations, or enter into new commercial arrangements requiring additional payments, could be materially and adversely affected.

**Risks Related to our Intellectual Property** Our success is largely dependent upon our patents, proprietary technology, and other intellectual property. Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. Patents and other proprietary rights are essential to our business. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. Our general policy has been to file patent applications to protect our inventions and improvements to our inventions that are considered important to the development of our business. In certain cases, we have chosen to protect our intellectual property by treating it as confidential internal know- how. Our success will depend in part on our ability to obtain patents, defend patents, maintain internal know- how / trade secret protection and operate without infringing on the proprietary rights of others. Interpretation and evaluation of pharmaceutical patent claims present complex legal and factual questions. Further, patent protection may not be available for some of the products or technology we are developing. If we are placed in a position where we must spend significant time and money defending or enforcing our patents, designing around patents held by others or licensing patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed. In seeking to protect our inventions using patents it is important to note that we have no assurance that: ● patent applications will result in the issuance of patents; ● additional proprietary products developed will be patentable; ● patents issued will provide adequate protection or any competitive advantages; ● patents issued will not be successfully challenged by third parties; ● commercial exploitation of our inventions does not infringe the patents or intellectual property of others; or ● we will be able to obtain any extensions of the patent term.

A number of pharmaceutical, biotechnology and medical device companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to our business. Some of these technologies, applications or patents could limit the scope of the patents, if any, that we may be able to obtain. It is also possible that these technologies, applications or patents may preclude us from obtaining patent protection for our inventions. Further, there may be uncertainty as to whether we may be able to successfully defend any challenge to our patent portfolio. Moreover, we may have to participate in derivation proceedings, inter partes review proceedings, post-grant review proceedings, or opposition proceedings in the various jurisdictions around the world. An unfavorable outcome in a derivation proceeding, an inter partes review proceeding, a post-grant review proceeding, or an opposition proceeding could preclude us or our collaborators or licensees from making, using or selling products using the technology, or require us to obtain license rights from third parties. It is not known whether any prevailing party would offer a license on commercially acceptable terms, if at all. Further, any such license could require the expenditure of substantial time and resources and could harm our business. If such licenses are not available, we could encounter delays or prohibition of the development or introduction of our product. In the case of intellectual property where we have chosen to protect it by treating it as internal knowhow, there can be no assurance that others with greater expertise or access to greater resources do not develop similar or superior technology that impairs the competitive value of our internal know-how. **Moreover, a number of aspects of intellectual property protection in the field of AI are currently under development, and there is uncertainty and ongoing litigation in different jurisdictions as to the degree and extent of protection warranted for AI and machine learning systems, as well as relevant system input and outputs. If we fail to obtain protection for the intellectual property rights concerning our AI technologies, or later have our intellectual property rights invalidated or otherwise diminished, our competitors may be able to take advantage of our research and development efforts to develop competing products, and our business, financial condition and operations could be materially and adversely impacted.** Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. The U. S. Patent and Trademark Office (, or “PTO” ,) and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees on any issued patent are due to be paid to the PTO and various foreign national or international patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our Product Candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business. We may become subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property. Our commercial success depends upon our ability to develop, manufacture, market and sell our Product Candidates, and to use our related proprietary technologies without violating the intellectual property rights of others. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our Product Candidates, including interference or derivation proceedings before the PTO or other international patent offices. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party’s intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our Product Candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing the applicable product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our Product Candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. While our preclinical studies are ongoing, we believe that the use of our Product Candidates in these preclinical studies fall within the scope of the exemptions provided by 35 U. S. C. Section 271 (e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our Product Candidates progress toward clinical trials and, ultimately, commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our Product Candidates and the methods we employ to manufacture them, as well as the methods for their uses we intend to promote, do not infringe other parties’ patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business. Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating

our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our current and former employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on all of our Product Candidates throughout the world would be prohibitively expensive. Therefore, we have filed applications and / or obtained patents only in key markets such as the United States, Canada, Japan and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may be able to export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, 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. For example, an April 2016 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. As a result, proceedings to enforce our patent rights in certain foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business and could be unsuccessful. Patent terms may be inadequate to protect our competitive position on our Product Candidates for an adequate amount of time. 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. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the PTO, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. For example:

- others may be able to make compounds that are the same as or similar to our Product Candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; or
- the patents of others may have an adverse effect on our business.

Risks Related to our Third

Parties We rely heavily on contract manufacturers over whom we have limited control. If we are subject to quality, cost or delivery issues with the preclinical and clinical grade materials supplied by contract manufacturers, our business operations could suffer significant harm. We currently have no manufacturing capabilities and rely on ~~contract development and manufacturing organizations, or~~ “CDMOs”, to manufacture our Product Candidates for preclinical studies and clinical trials. We rely on CDMOs for manufacturing, filling, packaging, testing, storing and shipping of drug products in compliance with cGMP, regulations applicable to our products. The FDA and other regulatory agencies ensure the quality of drug products by carefully monitoring drug manufacturers’ compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packaging of a drug product. If our CDMOs increase their prices or fail to meet our quality standards, or those of regulatory agencies such as the FDA, and cannot be replaced by other acceptable CDMOs, our ability to obtain regulatory approval for and commercialize our Product Candidates may be materially adversely affected. The APIs used in all of our Product Candidates are currently sourced from either contract manufacturers or, for smaller quantities, from research material suppliers, that typically utilize synthetic chemistry as their manufacturing method. This is intended to be an interim step to enable us to proceed with developing our formulation, execute preclinical toxicology studies and progress through Phase 1 and 2 clinical trials, after which time we anticipate that we will have been able to successfully scale- up our IntegraSyn manufacturing approach so that it will be GMP - ready at pharmaceutical grade. Bridging studies consisting of chemical analysis and, possibly, animal studies may be required in order to switch our APIs from the current external manufacturing sources to our internally manufactured products. There is no guarantee that we will be successful in scaling up our IntegraSyn manufacturing process for cannabinoids, or successfully complete any required bridging studies, or be able to successfully transfer our IntegraSyn manufacturing process to a CDMO. The key risks and challenges associated with the development of the IntegraSyn process include: failure to continue optimization and development of the process manufacturing steps from the current scale while maintaining the same or greater output of the selected cannabinoid; equipment and techniques may not be able to be scaled up using existing commercial processing equipment; supply of the key starting materials for the process may not be secured to ensure stability and security of commercial supply; and, failure of the large scale process to consistently produce the selected cannabinoid within set specifications and meeting the process parameters and in process controls to enable the manufacturing process to be validated for GMP commercial production of an API, among others. Failing to accomplish these or other criteria for the IntegraSyn manufacturing process with a CDMO may mean that we are not able to produce certain cannabinoids in a cost- effective manner. This could result in us not being able to successfully commercialize or utilize our APIs in our Product Candidates, if any, that may obtain regulatory approval. Our existing collaboration agreements and any that we may enter into in the future may not be successful. We also have relationships with scientific collaborators at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research and development strategies. These scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, companies that conflict in interests with and pose a competitive threat to us. Moreover, to the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements and our selected partners may be given, and may exercise, a right to terminate their agreement with us without cause. Our Collaborative Research Agreement with the University of British Columbia may be terminated by either party upon 30 calendar days written notice. The terms of any collaboration or other arrangements that we may establish may not be favorable to us. For all of the aforesaid reasons and others set forth in this Annual ~~Report Form on 10-K~~, an investment in ~~our common~~ **Common shares** ~~Shares~~ and any other securities that we may offer from time to time involves a ~~certain~~ **high** degree of risk. Any person considering an investment in our ~~common~~ **Common shares** ~~Shares~~ or any other of our securities should be aware of these and other factors set forth in this ~~Annual Report 10-K~~ and should consult with his or her legal, tax and financial advisors prior to making an investment in our ~~common~~ **Common shares** ~~Shares~~ or any other of our securities that may be offered from time to time. Our ~~common~~ **Common shares** ~~Shares~~ and any other securities that we may offer from time to time should only be purchased by persons who can afford to lose all of their investment. 76