



**LOBE SCIENCES LTD.**

**Management's Discussion & Analysis**

**For the years ended August 31, 2023 and 2022**

(Expressed in Canadian dollars)

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**MANAGEMENT'S DISCUSSION AND ANALYSIS**

This management's discussion and analysis ("MD&A") of the financial condition and results of operations of Lobe Sciences Ltd. and its subsidiaries ("Lobe", the "Company", or the words "we", "us" or "our"), prepared as at February 6, 2024, is for the years ended August 31, 2023 and 2022. This MD&A is a supplement to and should be read in conjunction with the Company's consolidated financial statements for the years ended August 31, 2023 and 2022 ("Financial Statements"). The Company's Financial Statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards ("IASB") and interpretations of the International Financial Reporting Interpretations Committee. All amounts presented herein are stated in Canadian dollars unless otherwise indicated. References to "USD" or "US\$" are to United States dollars. The first, second, third and fourth quarters of the Company's fiscal years are referred to as "Q1", "Q2", "Q3" and "Q4", respectively. The years ended August 31, 2023, and 2022, are referred to as "fiscal 2023", and "fiscal 2022", respectively.

This MD&A has been prepared by reference to the MD&A disclosure requirements established under National Instrument 51-102 *Continuous Disclosure Obligations* of the Canadian Securities Administrators. Additional information regarding Lobe is available through the SEDAR website at [www.sedarplus.ca](http://www.sedarplus.ca).

**FORWARD LOOKING INFORMATION**

This MD&A contains "forward-looking statements" that involve risks and uncertainties. Such information, although considered to be reasonable by the Company's management at the time of preparation, may prove to be inaccurate and actual results may differ materially from those anticipated in the statements made. This MD&A may contain forward-looking statements that reflect the Company's current expectations and projections about its future results. When used in this MD&A, words such as "estimate", "intend", "expect", "anticipate" and similar expressions are intended to identify forward-looking statements, which, by their very nature, are not guarantees of the Company's future operational or financial performance, and are subject to risks and uncertainties and other factors that could cause the Company's actual results, performance, prospects or opportunities to differ materially from those expressed in, or implied by, these forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this MD&A or as of the date otherwise specifically indicated herein. Due to risks and uncertainties, including the risks and uncertainties identified above and elsewhere in this MD&A, actual events may differ materially from current expectations.

Such statements reflect management's current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by the Company, are inherently subject to significant business, economic, competitive, political and social uncertainties and known or unknown risks and contingencies. Many factors could cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. Please see the risk factors discussed under the heading "Risks and uncertainties".

There is a significant risk that such forward-looking statements will not prove to be accurate. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Every patient treated on future studies can change those assumptions either positively (to indicate a faster timeline to new drug applications and other approvals) or negatively (to indicate a slower timeline to new drug applications and other approvals). This MD&A contains certain forward-looking statements regarding anticipated or possible drug development timelines. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date. In addition to the factors set out above and those identified in Company's MD&A under the heading "Risks and uncertainties", other factors not currently viewed as material could cause actual results to differ materially from those described in the forward-looking statements.

Although Lobe has attempted to identify important risks and factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors and risks that cause actions, events or results not to be anticipated, estimated or intended. Accordingly, readers should not place any undue reliance on forward-looking statements.

## **BUSINESS OVERVIEW**

Lobe was incorporated under the Business Corporations Act (British Columbia) on May 13, 2010. The head office, principal address and registered office of the Company are located at 1400 - 1199 West Hasting Street, Vancouver, B.C. V6E 3T5. The Company's common shares are listed under the symbol "LOBE" on the Canadian Securities Exchange and under the symbol "LOBEF" on the OTCQB.

On June 10, 2022, the Company consolidated its issued share capital on a ratio of six old common shares for every one new post-consolidated common share. All current and comparative references to the number of common shares, weighted average number of common shares, loss per share, share purchase options, share purchase warrants, performance warrants, restricted share units ("RSUs") and deferred share units ("DSUs") have been restated to give effect to this share consolidation.

Lobe is a biopharmaceutical company committed to discovering and developing patient-focused medicines for Orphan and Rare diseases. The Company, through collaborations with industry-leading partners, is engaged in drug research and development using sub-hallucinatory doses of proprietary psychedelic compounds to improve brain and mental health and wellness. Initially the Company will develop psilocin-based therapeutics for the treatment of severe forms of anxiety such as post-traumatic stress disorder, cluster headaches, and an undisclosed pediatric Orphan disease associated with severe anxiety. With our acquisition of Altemia & Company LLC ("Altemia") on April 17, 2023, we intend to commercialize a medical food named Altemia™ for the treatment of Sickle Cell Disease ("SCD").

## **HIGHLIGHTS**

### **For the years ended August 31, 2023 consolidated financial highlights**

- Net loss of \$4,708,302 or \$0.05 per share compared to net loss of \$12,252,852 or \$0.32 per share for the year ended August 31, 2022.

### **August 31, 2023 compared to August 31, 2022 consolidated balance sheet highlights**

- Total assets were \$2,299,491 compared to \$1,747,695 at August 31, 2022, an increase of 32%. This increase is mainly due to the intangibles asset which was acquired as a result of the Altemia acquisition, offset by spending during the year on research.
- Working capital deficiency was \$2,140,263 compared to \$266,084 at August 31, 2022, due to convertible notes issued in the period and increased research expenditures.

## **2023 BUSINESS DEVELOPMENT AND OVERVIEW**

Lobe is a biopharmaceutical company committed to discovering and developing patient-focused medicines for Orphan and Rare diseases. The Company, through collaborations with industry-leading partners, is engaged in drug research and development using non-hallucinatory doses of proprietary psilocin conjugate compounds to improve brain and mental health and wellness. With our acquisition of Altemia & Company LLC on April 17, 2023, we intend to commercialize a medical food named Altemia™ for the treatment of SCD. An update on business development for psilocin conjugate compounds and Altemia is provided below.

### **Psilocin Conjugate Compounds**

Lobe is currently working to develop effective non-hallucinatory psychedelic-based therapeutics for the treatment of severe forms of anxiety, cluster headaches ("CH") and an undisclosed pediatric Orphan disease associated with severe anxiety.

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Other than medicines that mask individual symptoms related to these conditions, there are currently few therapeutic options or US Food and Drug Administration ("FDA") approved drugs for the treatment of severe anxiety conditions and cluster headaches. The Company intends to prove that clinical and physiological outcomes are improved by administering doses of L-130 or L-131 our proprietary psilocin compounds. The Company plans to demonstrate these proprietary compounds elicit positive and meaningful clinical outcomes allowing patients to return to normal daily activities. Multiple studies evaluating the effect of psilocybin dosed at various levels were effective at lowering the frequency and intensity of CH. A 2006 study conducted at Harvard demonstrated that 85% of CH were aborted, 95% of treated patients experiences longer remission periods and 52% of patients experienced termination of the CH cycle<sup>1</sup>. A 2022 study conducted in Denmark examined the feasibility of dosing psilocybin as a prophylactic treatment in CH patients found that the incidence of headaches was decreased 30%, with one patient experiencing complete remission for 21 weeks of the study<sup>2</sup>.

The Company intends to sponsor and work with licensed third parties to conduct any clinical trials and research and does not handle or directly manufacture controlled substances. If the Company were to conduct this work without the reliance on third parties, it would need to obtain additional licenses and approvals described below.

#### **Relationships with Third Parties**

##### **Clearway Global LLC**

On June 21, 2022, the Company announced an exclusive agreement with Clearway Global LLC ("Clearway") to lead the Company's global regulatory and development strategy and its implementation.

##### **Ingenu Pty Ltd.**

On September 1, 2022, the Company announced that it plans to conduct Phase 1b/2a clinical trials in Australia with iNGENū Pty Ltd. ("iNGENū").

#### **Drug Development Program**

The following summarizes the drug development program for L-130 and L-131:

##### **L-130**

On July 12, 2022, the Company filed patent 63/388,414, for a proprietary form of psilocin ("L-130"). L-130 is a molecular modification of naturally occurring psilocin, which is the active component of psilocybin. On October 13, 2022, the Company, through an exclusive pharmaceutical discovery and development Agreement with QCL, an FDA licensed manufacturer, completed the synthesis of bulk L-130 and of the clinical supplies to be used in upcoming trials. The L-130 was manufactured in compliance with U.S. Current Good Manufacturing Practices ("cGMPs").

The exclusive pharmaceutical discovery and development agreement with QCL provides the Company with an exclusive source of L-130. Affirming our access to cGMP pharmaceutical grade active pharmaceutical ingredients will enable us to efficiently conduct clinical trials and plan for further work using these differentiated compounds to investigate the safety and tolerability of the drug candidate, L-130 and measure absolute pharmacokinetics of this new chemical entity ("NCE"). As the Company continues to progress through the L-130 program, additional milestones related to the Phase 1b/2a clinical trials have been identified.

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<sup>1</sup> Source: <https://n.neurology.org/content/66/12/1920>. Obtained July 19, 2023.

<sup>2</sup> Source: <https://www.medrxiv.org/content/10.1101/2022.07.10.22277414v1>. Obtained July 19, 2023.

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On June 27, 2023 the Company announced that it has successfully completed dosing of all test subjects in our first-in-man study of L-130. This Phase 1a study, conducted in Jordan under the authority of the Jordan Food and Drug Administration in compliance with the GCP and GLP regulatory requirements of the Declaration of Helsinki and the US FDA Guidelines for Bioavailability & Bioequivalence Studies, was an open label clinical trial in 10 normal and healthy individuals designed to determine the safety and pharmacokinetic parameters of L-130 after a single oral dose. All subjects will be evaluated for impacts on cognition and anxiolytic effects on day 1, 7 and 28. To date, all subjects have been dosed with no significant adverse events. Final data analysis and full completion of the study is expected in Q1 2024. The results of this study and potentially additional Phase 1 studies will be used to determine the dose range of L-130 for a planned Phase 2 trial targeting the treatment of chronic cluster headaches, the most predominant headache disorder within the group of trigeminal autonomic cephalgias<sup>3</sup>.

As previously announced in January 2023, the Company is in discussions with Integrative Headache Medicine of New York, to study the tolerability and efficacy of our proprietary psilocin compound L-130, in patients suffering from CH. We expect to update our progress on this study planning as we finalize agreements with all connected parties and final protocol design is completed.

The Company is preparing an Investigational New Drug Application ("IND") application and meeting request for filing with the FDA to confirm its regulatory strategy and clinical protocols. We plan to file the IND when we have completed additional clinical and pre-clinical studies. Following FDA's input and clearance of our IND, clinical trials may be initiated in the United States<sup>3</sup>.

The Company intends to partially fund L-130 research in Australia with proceeds from convertible note financing bearing interest at 15% per annum with a term of 12 months (the "Convertible Notes") with Cantheon Capital ("Cantheon"). The Company intends to partially complete future clinical trials for this program in Australia through our research partner iNGENū and other international Contract Research Organizations (CRO). There is no assurance that the aforementioned timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, regulatory guidelines for developing a drug with Ph 1 safety studies, Ph 2 proof of concept studies, and Ph 3 pivotal studies to generate data in support of a New Drug Application ("NDA") submission. Our plans are prepared to provide the best opportunities for the successful implementation and generate the results of such studies on timelines indicated regulatory guidelines, other industry examples, and the Company's development efforts to date.

### **L-131**

On July 7, 2022, the Company announced the advancement of a second NCE, L-131 as our second NCE to enter clinical development. The exclusive pharmaceutical discovery and development agreement with QCL provides the Company with an exclusive source of L-131. Affirming our access to cGMP pharmaceutical grade active pharmaceutical ingredients will enable us to efficiently conduct pre-clinical and clinical trials to investigate the safety and tolerability of the drug candidate, L-131 by measuring absolute pharmacokinetics of this NCE. As the Company continues to progress through the L-131 program, additional milestones related to the clinical trials will be identified.

The Company intends to:

- provide results of preclinical rodent studies in the first quarter of 2024 which will evaluate its safety and pharmacokinetics and support our Orphan Drug application; and
- pending positive results for the pre-clinical trial the Company will file an IND for initiating clinical trials in children<sup>3</sup>.

The Company is investigating filing a Pediatric Orphan Drug application with the FDA using L-131 in the second half of 2023. If approved by the FDA this Orphan Drug indication may qualify the Company for a Priority Review Voucher from the FDA<sup>4</sup>.

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<sup>3</sup> There is no assurance that the aforementioned timeline will be met or that the program will advance to clinical trials, at all. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.

<sup>4</sup> This statement is based on the following material assumption: drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. As of the date hereof, it has not yet completed the aforementioned items. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date. See "Risk Factors".

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The Company intends to complete future clinical trials for this program in Australia, North America and Europe. There is no assurance that the timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, regulatory guidelines for developing a drug with Ph 1 safety studies, Ph 2 proof of concept studies, and Ph 3 pivotal studies to generate data in support of an NDA submission. Our plans are prepared to provide the best opportunities for the successful implementation and generate the results of such studies on timelines indicated regulatory guidelines, other industry examples, and the Company's development efforts to date.

**Intellectual Property**

The Company, through its wholly owned subsidiary Eleusian Biosciences Corp., has title to provisional patent applications as summarized below.

	<b>Patent Application Number</b>	<b>Date of Application</b>	<b>Expiry</b>	<b>Jurisdiction</b>	<b>Status</b>	<b>Description</b>
1	2021358135	April 20, 2021	April 20, 2041	Australia	Pending	Methods for Treating Mild Traumatic Brain Injury, Post Traumatic Stress Disorder, and Mild Traumatic Brain Injury
2	3,176,225	April 20, 2021	April 20, 2041	Canada	Pending	Methods for Treating Mild Traumatic Brain Injury, Post Traumatic Stress Disorder, and Mild Traumatic Brain Injury
3	21792649.2	April 20, 2021	April 20, 2041	Europe	Pending	Methods for Treating Mild Traumatic Brain Injury, Post Traumatic Stress Disorder, and Mild Traumatic Brain Injury
4	17/916,855	April 20, 2021	April 20, 2041	United States	Pending	Methods for Treating Mild Traumatic Brain Injury, Post Traumatic Stress Disorder, and Mild Traumatic Brain Injury
5	63/388,414	July 12, 2022	July 12, 2023	United States	Pending	Preparation of Stable Psilocin Salts and Uses Thereof
6	63/390,451	July 19, 2022	July 19, 2023	United States	Pending	Confidential Pediatric Orphan Disease

**Regulatory Framework and Licensing Regimen**

The Company intends to sponsor and work with licensed third parties to conduct any clinical trials and research and does not handle controlled substances. If the Company were to conduct this work without the reliance on third parties, it would need to obtain additional licenses and approvals described below.

## **Canada**

In Canada, oversight of healthcare is divided between the federal and provincial governments. The federal government is responsible for regulating, among other things, the approval, import, sale, and marketing of drugs such as psilocybin and other psychedelic substances, whether natural or novel. The provincial/territorial level of government has authority over the delivery of health care services, including regulating health facilities, administering health insurance plans such as the Ontario Health Insurance Plan, distributing prescription drugs within the province, and regulating health professionals such as doctors, psychologists, psychotherapists and nurse practitioners. Regulation is generally overseen by various colleges formed for that purpose, such as the College of Physicians and Surgeons of Ontario. Certain psychoactive compounds, such as psilocybin, are considered controlled substances under Schedule III of the Controlled Drugs and Substances Act (Canada) (the "CDSA"). In order to conduct any scientific research, including preclinical and clinical trials, using psychoactive compounds listed as controlled substances under the CDSA, an exemption under Section 56 of the CDSA ("Section 56 Exemption") is required. This exemption allows the holder to possess and use the controlled substance without being subject to the restrictions set out in the CDSA. The Company has not applied for a Section 56 Exemption from Health Canada. The possession, sale or distribution of controlled substances is prohibited unless specifically permitted by the government. A party may seek government approval for a Section 56 Exemption to allow for the possession, transport or production of a controlled substance for medical or scientific purposes. Products that contain a controlled substance such as psilocybin cannot be made, transported or sold without proper authorization from the government. A party can apply for a Dealer's Licence under the Food and Drug Regulations (Part J). In order to qualify as a licensed dealer, a party must meet all regulatory requirements mandated by the regulations including having compliant facilities, compliant materials and staff that meet the qualifications under the regulations of a senior person in charge and a qualified person in charge. Assuming compliance with all relevant laws (Controlled Drugs and Substances Act, Food and Drugs Regulations) and subject to any restrictions placed on the licence by Health Canada, an entity with a Dealer's Licence may produce, assemble, sell, provide, transport, send, deliver, import or export a restricted drug (as listed in Part J in the Food and Drugs Regulations - which includes psilocybin and psilocin) (see s. J.01.009 (1) of the Food and Drug Regulations).

## **United States**

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, clinical testing, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of any prescription drug product candidates or commercial products. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market. The Company intends to file an IND application related to L-130 for one or more clinical indications<sup>5</sup>. Anticipated timelines related to regulatory filings are based on reasonable assumptions informed by current knowledge and information available to the Company. Psilocybin and psilocin are strictly controlled under the federal Controlled Substances Act, 21 U.S.C. §801, et. seq. ("CSA") as Schedule I substances. Schedule I substances by definition have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the United States Drug Enforcement Administration ("DEA") and obtain DEA approval of the research proposal. A majority of state laws in the United States classify psilocybin and psilocin as Schedule I controlled substances. For any product containing psilocybin or any Schedule I substance to be available for commercial marketing in the United States, such substance must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance.

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<sup>5</sup> This statement is based on the following material assumption: drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. As of the date hereof, it has not yet completed the aforementioned items. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date. See "Risk Factors".

## **Altemia**

SCD is a group of hereditary red blood cell disorders. Healthy red blood cells are round, and they move through small blood vessels to carry oxygen to all parts of the body. In someone who has SCD, the red blood cells ("RBC") become inflamed under certain stress conditions resulting in among other symptoms, an increase of C-Reactive Protein (a biomarker for SCD). Inflammation causes the RBC's membrane to become hard and sticky, and this tends to slow or even block blood flow in the blood vessels (capillaries) of the limbs and organs. This slowing of the blood cells causes a cascade of events that results in pain and vaso-occlusive event. The sickle cells die earlier than normal red blood cells and the bone marrow cannot make enough new red blood cells to replenish the dying ones, which causes a constant shortage of red blood cells called anemia. Blocked blood flow may cause pain and other serious problems such as infection, acute chest syndrome and stroke. Populations that suffer from SCD have a shortened life span.

According to the CDC, it is estimated that SCD affects approximately 100,000 individuals in the United States, occurring among approximately 1 out of every 500 Black or African American births and 1 out of every 36,000 Hispanic American births. A similar number of patients are affected in Europe. There are millions of patients in the Middle East, Africa and India<sup>6</sup>.

Altemia™ is the brand name of a patent pending oral emulsion consisting of a proprietary mixture of polyunsaturated fatty acid triglyceride esters clinically evaluated to reduce inflammation associated in adults with SCD. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." SCD is among a few inborn errors of metabolism specifically named in legislation that qualifies as treatable with medical foods.

On April 17, 2023, the Company signed a share purchase agreement with Sancillio, LLC to acquire a 100% interest in Altemia which includes all assets, know-how, intellectual property and commercial inventory to manage patients suffering from SCD. The Company plans to sell Altemia™ globally, either directly or through partners, and expects to generate sales and cash flow in the second half of calendar 2023. Altemia has no current or long-term liabilities. Pursuant to the Agreement, Altemia shareholders received total of 76,000,000 common shares of Lobe ("Lobe Shares") at a deemed issue price of \$0.05 per Lobe Share. The Lobe Shares were subject to certain restrictions on transfer. On August 30, 2023, the Company signed an amendment to its April 17, 2023 share purchase agreement to acquire a 100% interest in Altemia ("Amendment"). Pursuant to the Amendment, the 76,000,000 common shares of the Company (each a "Lobe Share") previously issued to the Selling Members were returned and cancelled by Lobe pursuant a share cancellation agreement.

Pursuant to the Amendment, the 76,000,000 Lobe Shares shall be reissued upon the later of:

1. Achievement of the following milestones:
  - a. 25% on or after the Amendment closing date;
  - b. 25% on delivery of inventory to a Lobe designated storage facility;
  - c. 25% on the first commercial sale allowing the trademark validation; and
  - d. 25% on successful completion of SAN100 Tech Transfer Documentation and samples of SAN100 are delivered to Lobe.
2. Within ten days of Selling Members providing Lobe a written notice to release some or all of the then available shares with respect to which the applicable Milestone has been met. Each Altemia member may in such notice designate one or more third parties to receive some or all of any such Lobe Shares then available for release.

Lobe will issue 3,000,000 warrants contingent on Altemia achieving \$20,000,000 in cumulative sales ("Contingent Warrants"). Pricing of the Contingent Warrants will be determined in accordance with the relevant CSE policy.

Sancilio LLC is owned by Fred and Alex Sancilio who are also owners to Clearway. Pursuant to the share exchange agreement, Altemia can appoint one member to the Company's Board of Directors. It is expected that Fred Sancilio will be appointed to the Company's board of directors in the coming weeks.

The Company will pay a tiered royalty on annual net sales and issue 3,000,000 warrants upon the first achievement of US\$20,000,000 in cumulative sales. The transaction provides a 5% payment on the net sales revenue received for the sale of a pediatric priority review voucher for the approval of our SCD prescription drug for the pediatric orphan indication.

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<sup>6</sup> Source: <https://www.cdc.gov/ncbddd/sicklecell/data.html>. Obtained April 26, 2023



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On May 5, 2023, the Company announced an exclusive distribution agreement with Pentec Health Inc. ("Pentec"). In the ensuing months we have been working closely with Pentec planning all facets of the commercial launch for Altemia™. During the year ended August 31, 2023, the Company shipped Altemia™ inventory to Pentec and recorded sales revenue of \$840,531 (US\$619,500).

**Intellectual Property**

The Company, through Altemia, holds a licensing agreement which grants a worldwide, nontransferable, non-sublicensable, exclusive right to make, have made, use, offer to sell, sell, and import licensed products utilizing the Patent Cooperation Treaty ("PCT") application as summarized below.

Patent Application Number	Date of Application	Expiry	Jurisdiction	Status	Description
1 PCT/US2021/021879	March 11, 2021	March 11, 2041	Europe, USA, Saudi Arabi, and the United Arab Emirates	Pending	A composition comprising docosahexaenoic acid and egg yolk suitable for sickle cell disease treatment

**SUMMARY OF QUARTERLY RESULTS**

	Q4 2023	Q3 2023	Q2 2023	Q1 2023
Net loss from continuing operations	<b>(1,375,840)</b>	(312,101)	(1,001,973)	(2,017,435)
Net income from discontinued operations	-	-	-	-
Comprehensive loss	<b>(1,378,439)</b>	(310,651)	(1,001,777)	(2,017,435)
Basic and diluted net loss per share	<b>(0.01)</b>	(0.00)	(0.01)	(0.03)
Number of weighted average shares – basic and diluted	<b>134,234,357</b>	114,291,584	76,837,215	70,575,069

	Q4 2022	Q3 2022	Q2 2022	Q1 2022
Net loss from continuing operations	(2,604,068)	(1,961,634)	(3,112,634)	(4,574,516)
Net loss from discontinued operations	-	-	-	-
Comprehensive loss	(2,604,068)	(1,961,634)	(3,112,634)	(4,574,516)
Basic and diluted loss per share	(0.07)	(0.05)	(0.08)	(0.12)
Number of weighted average shares – basic and diluted	38,442,056	38,712,285	37,438,997	37,438,997

The Company reported lower net loss from continuing operations as a result of a loss from fair value changes on preferred shares and common shares received as consideration for the sale of the of certain assets relating to Washington-based Cowlitz, an impairment of dividends receivable on the preferred shares received on the sale of Cowlitz being recognized in prior periods.

**COMPARISON OF RESULTS**

A summary of the Company's financial condition based on and derived from the Financial Statements, is as follows:

	Fiscal 2023	Fiscal 2022	Fiscal 2021
	\$	\$	\$
Net loss	<b>(4,707,349)</b>	(12,252,852)	(9,658,418)
Basic and diluted loss per share	<b>(0.05)</b>	(0.32)	(0.12)

	2023	2022	As at August 31, 2021
	\$	\$	\$
Cash	<b>140,290</b>	907,537	1,141,839
Total assets	<b>2,299,491</b>	1,747,695	12,097,848
Total liabilities	<b>2,459,618</b>	1,302,005	804,701
Share capital	<b>27,623,599</b>	25,221,396	24,841,218
Total shareholders' (deficiency) equity	<b>(160,127)</b>	445,690	11,293,247

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A summary of the Company's results of operations for the three months ended and years ended August 31, 2023 and 2022 is as follows:

	<b>Q4 2023</b>	<b>Q4 2022</b>	<b>Fiscal 2023</b>	<b>Fiscal 2022</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Revenue	<b>840,534</b>	-	<b>840,534</b>	-
Cost of sales	<b>(24,012)</b>	-	<b>(24,012)</b>	-
Gross profit	<b>816,522</b>	-	<b>816,522</b>	-
Advertising	<b>34,950</b>	79,423	<b>289,031</b>	248,134
Amortization	<b>24,590</b>	10,222	<b>43,696</b>	10,222
Consulting fees	<b>(627,664)</b>	368,139	<b>1,280,460</b>	1,621,825
General and administrative	<b>43,487</b>	35,940	<b>173,762</b>	198,861
Insurance	<b>93,329</b>	107,794	<b>368,135</b>	356,593
Professional fees	<b>194,154</b>	344,290	<b>471,516</b>	648,620
Research	<b>992,419</b>	94,806	<b>1,247,540</b>	418,343
Share-based compensation	<b>128,758</b>	121,330	<b>301,768</b>	620,612
Operating loss	<b>884,023</b>	1,161,944	<b>3,359,386</b>	4,123,210
Other expenses	<b>1,103,339</b>	1,442,124	<b>1,142,963</b>	8,129,642
Income tax expense	<b>205,000</b>	-	<b>205,000</b>	-
Net loss	<b>2,192,362</b>	2,604,068	<b>4,707,349</b>	12,252,852

Q4 2023 compared to Q4 2022:

The Company reported a net loss of \$1,375,840 compared to a loss of \$2,604,068 in the prior year comparable period. The primary driver of this decrease in the net loss is as follows:

- Revenue increased to \$840,534 compared to \$nil in the prior year comparable period due to sales of Altemia™, which did not occur prior to fiscal 2023.
- Other expenses includes accretion expense, dividend income, foreign exchange loss, change in fair value of derivative liability, gain on debt settlement, impairment of investment in Krysalis, impairment of promissory notes receivable, interest expense, change in fair value of common shares, change in fair value of preferred shares, change in fair value of warrants, and share of loss in Krysalis. During Q4 2023, the Company incurred loss of \$74,251 compared to a loss of \$1,442,124 in the prior year comparable period. The loss in Q4 2023 results from impairment of investment in Krysalis, partially offset by gain in debt settlement. The loss in Q4 2022 resulted from a non-cash decrease in loss on change in fair value of common shares and loss on change in fair value of preferred shares as the balances were fully impaired as at August 31, 2023.

Partially offsetting the decrease in the net loss were increases to expenses as follows:

- Research expenses recovery to \$992,419 compared to \$94,806 in the prior year comparable period due to expenses in connection with the preparation for preclinical studies for L-130 and 4L-131, which includes a consulting fee with our manufacturing partner QCL. The Company and its exclusive partners have initiated formal import and export permitting activities within the United States and countries abroad.

Fiscal 2023 compared to fiscal 2022:

The Company reported a net loss of \$4,707,349 compared to a loss of \$12,252,852 in the prior year. The primary drivers of this decrease in the net loss are as follows:

- Revenue increased to \$840,534 compared to \$nil in the prior year due to sales of Altemia™, which did not occur prior to fiscal 2023.
- Consulting fees decreased to \$1,280,460 compared to \$1,621,825 in the prior year due to consulting agreements with various advisors for corporate communications and business development activities in fiscal 2022 that did not occur in fiscal 2023. The expense for fiscal 2023 also includes expenses related to executive consulting agreements with the Chief Executive Officer, Chief Science Officer, and Clearway related to our global regulatory and development strategy and its implementation.

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- Share-based compensation decreased to \$301,768 compared to \$620,612 in the prior year. The Company uses the Black-Scholes option pricing model for options, RSUs and DSUs granted to officers, management, and consultants. Share-based compensation expense decreased during fiscal 2023 as compared to fiscal 2022 due to the reversal of expenses associated with unvested RSUs and DSUs which were cancelled pursuant to the mutual separation agreement with the former Executive Chairman.

Partially offsetting the decrease in the net loss were increases to expenses as follows:

- Research expense increased to \$1,247,540 compared to \$418,343 in the prior year. The fiscal 2023 expenses were incurred in connection with the preparation for preclinical studies for L-130 and L-131, which includes a consulting fee with our manufacturing partner QCL and the fair value of 1,000,000 share purchase warrants issued on February 2, 2023. The Company and its exclusive partners have initiated formal import and export permitting activities within the United States and Countries abroad.
- Other expenses includes accretion expense, agreement termination expense, dividend income, foreign exchange loss, gain on change in fair value of derivative liability, gain on debt settlement, impairment of investment in Krysalis, impairment of promissory notes receivable, interest expense, loss on change in fair value of common shares, loss on change in fair value of dividend receivable, loss on change in fair value of preferred shares, loss on change in fair value of warrants, other income, and share of loss in Krysalis. During fiscal 2023, the Company incurred a loss of \$1,142,963 compared to \$8,129,642 during fiscal 2022. The decrease in loss is due to a non-cash decrease in loss on change in fair value of common shares and loss on change in fair value of preferred shares as the balances were fully impaired as at August 31, 2022, and gain on debt settlement primarily resulting from the settlement agreement with the University of Miami. This was partially offset by agreement termination expenses resulting mutual separation agreements with the former Executive Chairman of the Company and with an arm's length independent consultant entered in fiscal 2023 and impairment of investment in Krysalis in fiscal 2023.

## **LIQUIDITY, CASH FLOWS AND CAPITAL RESOURCES**

### **a) Liquidity**

Liquidity risk is the risk that the Company will encounter difficulties in meeting obligations associated with its financial liabilities and other contractual obligations. The Company's strategy for managing liquidity is based on the sale of preferred shares and dividend receivable, accessing capital markets through equity financing and achieving positive cash flows from operations to internally fund operating and capital requirements.

Factors that may affect the Company's liquidity are continuously monitored. These factors include fair value of the preferred shares and dividend receivable, patent application costs, research and development costs to develop the Company's patents, operating costs, capital costs, income tax refunds, foreign currency fluctuations, market immaturity and a highly fluid environment related to state and federal law passage and regulations. The Company's main use for liquidity is to fund the development of its research programs as noted above. The primary source of liquidity has been from public financing to date. The ability to fund operations, to make planned capital expenditures and execute the growth/acquisition strategy depends on the future operating performance and cash flows, which are subject to prevailing economic conditions, regulatory and financial, business and other factors, some of which are beyond the Company's control.

In the event that the Company is adversely affected by any of these factors and, as a result, the operating cash flows are not sufficient to meet the Company's working capital requirements there is no guarantee that the Company would be able to raise additional capital on acceptable terms to fund a potential cash shortfall. Consequently, the Company is subject to liquidity risk.

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A summary of the Company's working capital deficiency is as follows:

	August 31, 2023	August 31, 2022
	\$	\$
Cash	140,290	907,537
Receivables	14,915	18,282
Inventory	16,979	-
Prepaid expenses and deposits	147,171	110,102
Total current assets	319,355	1,035,921
Accounts payable and accrued liabilities	1,921,978	1,302,005
Income tax payable	205,000	-
Convertible notes	332,640	-
Derivative liability	-	-
Total current liabilities	2,459,618	1,302,005
Working capital deficiency	<b>(2,140,263)</b>	<b>(266,084)</b>

The Company incurred a net loss of \$4,707,349 during the year ended August 31, 2023. As at August 31, 2023, the Company has an accumulated deficit of \$35,682,375. These factors form a material uncertainty that may raise significant doubt regarding the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon the Company's ability to raise sufficient financing to acquire or develop a profitable business. The Company intends on financing its future development activities and operations from the sale of equity securities and through debt financing through Convertible Notes. Management will continue to monitor and assess its capital resources to meet operating requirements over the next twelve months.

**b) Cash Flows**

Review of cash flow for the years ended August 31, 2023 and 2022:

	August 31, 2023	August 31, 2022
<i>Net cash provided by (used in)</i>	\$	\$
Operating activities	<b>(1,718,644)</b>	(2,730,729)
Investing activities	-	1,743,311
Financing activities	950,013	753,116
Effect of exchange rate on cash	1,384	-
Cash, beginning of period	907,537	1,141,839
Cash, end of period	<b>140,290</b>	907,537

Cash used in operating activities during fiscal 2023 was \$1,718,644 compared to cash used in operating activities of \$2,730,729 during fiscal 2022. The net change in cash from operating activities during the three months ended August 31, 2023 compared to the year ended August 31, 2022 was attributable to the following:

- Net loss of \$4,707,349 compared to net loss from continuing operations of \$12,252,852 due primarily to non-cash changes in fair value of preferred shares, changes in fair value of short-term investments, share-based compensation for the year ended August 31, 2022. Included in net loss are non-cash items of \$1,472,361 for the year ended August 31, 2023 compared to \$8,674,594 for the year ended August 31, 2022.
- Movements in receivables increased cash by \$3,367 compared to a \$177,425 increase for the year ended August 31, 2022.
- Movements in prepaid expenses decreased cash by \$37,069 compared to a \$172,800 increase for the year ended August 31, 2022.
- Movements in accounts payable and accrued liabilities increased cash by \$1,321,099 compared to increasing cash by \$497,304 for the year ended August 31, 2022.
- Movements in tax payable increased cash by \$205,000 compared to \$nil for the year ended August 31, 2022.

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Cash provided by investing activities for the year ended August 31, 2023 was \$nil as compared to \$1,743,311 during the year ended August 31, 2022. Cash used in investing activities during the year ended August 31, 2022 were the result of sale of common shares of Ionic which had been acquired on sale of the Cowlitz.

Cash provided by financing activities for the year ended August 31, 2023 was \$950,013 as compared to \$753,116 during the year ended August 31, 2022. Movements during fiscal 2023 were the result of funds raised through private placement, issuance on convertible notes, the exercise of share purchase options, and the exercise of share purchase warrants which were partially offset by share issue costs.

**c) Capital Resources**

The capital of the Company consists of consolidated equity, net of cash.

	August 31, 2023	August 31, 2022
	\$	\$
Cash	140,290	907,537
Receivables	14,915	18,282
Less:		
Accounts payable and accrued liabilities	(1,921,978)	(1,302,005)
Convertible notes	(332,640)	-
Derivative liability	-	-
Net capital	(2,099,413)	(376,186)
Add:		
Equity	(160,127)	445,690
Net capital and equity	(2,259,540)	69,504

The Board of Directors of the Company has overall responsibility for the establishment and oversight of the Company's risk management policies on an annual basis. The Company's board of directors identifies and evaluates the Company's financial risks and is charged with the responsibility of establishing controls and procedures to ensure financial risks are mitigated. The Company's objectives when managing capital are to maintain adequate capital resources to fund development of the Company's patents, operating costs and capital costs. The Company does not have any externally imposed capital requirements to which it is subject. The Company manages the capital structure and adjusts it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Company may attempt to issue new common shares for cash consideration. The Company's investment policy is to invest excess cash in investment instruments at high credit, quality financial institutions with terms to maturity selected with regards to the expected time of expenditures from continuing operations.

**PROPOSED TRANSACTIONS**

There are no proposed transactions under consideration as of August 31, 2023 or the date of this report.

**OFF-BALANCE SHEET ARRANGEMENTS**

The Company does not have any off-balance sheet arrangements such as guarantee contracts, contingent interests in assets transferred to unconsolidated entities, derivative financial obligations, or arrangements with respect to any obligations under a variable interest equity arrangement.

**CONTINGENCY**

On April 20, 2022, the Company entered a voting support and lock-up agreement ("VLA") with Ionic and Yourway Cannabis Brands Inc. ("Yourway"). The VLA is contingent on the execution of a plan of arrangement between Yourway and Ionic (the "Plan of Arrangement") in which Yourway would acquire all Ionic issued and outstanding common shares and preferred shares. There is no expiry date for the Plan of Arrangement; however, it may be cancelled if Ionic and Yourway mutually consent or by either party if certain conditions are not met. As at August 31, 2023, the Plan of Arrangement had not been cancelled and had not been executed. Due to the contingent nature of the VLA, the Company has not reflected the impact of the VLA in these interim financial statements.

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Pursuant to the VLA, the Company agreed to the following on the effective date of the Plan of Arrangement:

- convert 36,707,180 Ionic preferred shares to Ionic common shares resulting in the Company holding 57,229,991 Ionic common shares;
- convert 57,229,991 Ionic common shares to Yourway common shares at an exchange ratio of 0.0525 Yourway common shares for each Ionic common share resulting in the Company holding approximately 3,000,000 Yourway common shares;
- enter into an escrow agreement for the Yourway common shares held by the Company whereby the Yourway common shares will be released quarterly in 5 equal tranches commencing 12 months from the effective date of the Plan of Arrangement;
- accept 9,900,000 Ionic common share purchase warrants (the "Consideration Warrants") with each Consideration Warrant entitling the Company to acquire one Ionic common share at \$0.05 per Ionic common share for three years from the date of issuance in exchange for forgiveness of the dividend receivable; and
- convert the 4,000,000 Warrants and 9,900,000 Consideration Warrants, at an exchange ratio of 0.0525, into warrants exercisable into approximately 720,000 Yourway common shares at an exercise price of \$0.95

**RELATED PARTY DISCLOSURES**

Key management personnel include those who have the authority and responsibility of planning, directing and executing the activities of the Company. Key management includes directors of the Company, Chief Executive Officer, Executive Chairman, Chief Financial Officer, Chief Science Officer, Chief Operating Officer and former Executive Chairman. Other than the amounts disclosed above, there was no other compensation paid or payable to key management for employee services for the reported periods.

A summary of the Company's related party transactions for the years ended August 31, 2023 and 2022, is as follows:

	<b>Fiscal 2023</b>	Fiscal 2022
	\$	\$
Consulting fees	<b>1,028,149</b>	814,309
Directors' fees included in consulting fees	<b>162,000</b>	187,994
Professional fees	<b>121,155</b>	137,766
Share-based compensation	<b>160,715</b>	321,027
	<b>1,472,019</b>	1,461,096

Professional fees included in the table above were charged by a company related to the Chief Financial Officer.

Share-based compensation represents the expense recognized during the period for vesting of share purchase options, RSUs and DSUs.

A summary of the Company's consulting fees paid to related parties for the years ended August 31, 2023 and 2022, as per consulting agreement, is as follows:

	<b>Fiscal 2023</b>	Fiscal 2022
	\$	\$
Former Executive Chairman	<b>30,173</b>	444,785
Chief Executive Officer and Executive Chairman	<b>235,658</b>	280,018
Chief Science Officer	<b>147,942</b>	89,506
Chief Operating Officer	<b>55,343</b>	-
Clearway	<b>559,033</b>	-
	<b>1,028,149</b>	814,309

A summary of the Company's amounts due to related parties is as follows:

	<b>August 31, 2023</b>	August 31, 2022
	\$	\$
Accounts payable and accrued liabilities	<b>412,070</b>	106,664

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A summary of the Company's accounts payable and accrued liabilities per related party is as follows

	<b>August 31, 2023</b>	August 31, 2022
	<b>\$</b>	<b>\$</b>
Chief Executive Officer, for consulting fees	<b>16,955</b>	27,561
Chief Science Officer, for consulting fees	<b>108,361</b>	13,111
Company related to the Chief Financial Officer, for professional fees	<b>17,758</b>	10,763
Director	<b>334,876</b>	55,229
	<b>477,950</b>	106,664

On October 3, 2022, the Company entered into a mutual separation agreement with the former Executive Chairman of the Board of Directors of the Company. As part of the agreement, the Company agreed to issue an aggregate of 5,300,836 common shares of the Company for total consideration of \$556,588, which was recorded as agreement termination expense.

### **FINANCIAL INSTRUMENTS**

IFRS 13 - *Fair Value Measurement* establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs.

The three levels of the fair value hierarchy are as follows:

Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities;

Level 2 - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. from derived prices); and

Level 3 - Inputs for the asset or liability that are not based on observable market data.

The fair value of cash is measured using Level 1 inputs. The carrying value of accounts payable and accrued liabilities approximate their respective fair values due to the short-term nature of these instruments.

The fair value of Ionic common shares, dividend receivable, promissory note receivable, Ionic preferred shares and Warrants are measured using Level 2 inputs and are measured at fair value through profit or loss. The valuation methodology and significant assumptions for the Ionic preferred shares and dividend receivable are disclosed in Note 8(a) of the Financial Statements, Ionic common shares is disclosed in Note 8(b) of the Financial Statements, Warrants is disclosed in Note 9 of the Financial Statements and promissory note receivable in Note 10 of the Financial Statements.

The convertible notes and derivative liability are measured using Level 3 as disclosed in Note 14 and Note 15 of the Financial Statements.

The Company examines its various financial risks to which it is exposed and assesses the impact and likelihood of occurrence. The risks may include credit risk, currency risk, liquidity risk and interest rate risk. The Company's risk management program strives to evaluate the unpredictability of financial markets and its objective is to minimize the potential adverse effects of such risks on the Company's financial performance, where financially feasible to do so.

When deemed material, these risks may be monitored by the Company's finance group, and they are regularly discussed with the Board of Directors.

#### **a) Credit risk**

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to fulfill its contractual obligations. The Company's credit risk is predominantly related to cash balances held in financial institutions, receivables, and promissory note receivable. The Company minimizes its credit risk related to cash and cash equivalents by placing cash with major financial institutions. The Company does not invest in asset-backed deposits or investments and does not expect any credit losses. The Company periodically assesses the credit quality of its financial institutions and is satisfied with the credit ratings of its banks.

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**b) Foreign exchange risk**

Foreign exchange risk arises on financial instruments that are denominated in a currency other than the functional currency in which they are measured. The Company is exposed to foreign exchange risk from fluctuations in United States dollars and Australian dollars. The Company does not use derivative instruments to reduce its exposure to foreign exchange risk.

**c) Liquidity risk**

Liquidity risk is the risk that the Company will not be able to meet its financial obligations when they become due. To mitigate this risk, the Company has a planning and budgeting process in place to determine the funds required to support its ongoing operations and capital expenditures.

**d) Interest rate risk**

Interest rate risk is the risk that future cash flows will fluctuate as a result of changes in market interest rates. The Company is not exposed to interest rate risk.

The Company manages its capital to maintain its ability to continue as a going concern and to provide returns to shareholders and benefits to other stakeholders. The Company's capital structure consists of all components of shareholders' equity. The Company's objective when managing capital is to maintain adequate levels of funding to support the current operations including corporate and administrative functions to support operations. The Company obtains funding primarily through issuing common share. Future financing is dependent on market conditions and there can be no assurance the Company will be able to raise funds in the future.

**OUTSTANDING SHARE DATA**

As of the date of this MD&A, the Company's authorized share capital consists of an unlimited number of common shares without par value. The Company had the following securities outstanding as at February 6, 2024.

<b>Type of Security</b>	<b>August 31, 2023</b>	<b>Date of this MD&amp;A</b>
	<b>#</b>	<b>#</b>
Common Shares	<b>79,136,172</b>	79,136,172
Share Purchase Options	<b>8,611,479</b>	8,369,812
Performance Warrants	<b>776,000</b>	776,000
Share Purchase Warrants	<b>30,986,216</b>	30,716,133
Restricted Share Units	<b>5,175,000</b>	4,743,750
Deferred Share Units	<b>1,240,004</b>	1,240,004
	<b>125,924,871</b>	124,981,871

**INTERNATIONAL FINANCIAL REPORTING STANDARDS**

The Financial Statements have been prepared in accordance with IFRS as issued by the IASB, effective as of August 31, 2023. The accounting policies applied in the preparation of the Interim Financial Statements are consistent with those applied and disclosed in Note 3 to the audited consolidated financial statements.

**SIGNIFICANT ACCOUNTING POLICIES AND CRITICAL ACCOUNTING ESTIMATES**

All significant accounting policies and critical accounting estimates are fully disclosed in the notes to the Financial Statements for the years ended August 31, 2023 and 2022.



## **RISKS AND UNCERTAINTIES**

Any investment in the securities of the Company is speculative, due to the nature of its business and its general stage of development. These risk factors could materially affect the Company's future operating results and could cause actual events to differ materially from those described in forward looking statements relating to the Company. In addition to the usual risks associated with investment in a business, investors should carefully consider the following risk factors as well as the risk factors set out in the Company's other public disclosure.

The Company's business and results of operations are subject to a number of risks and uncertainties, including but not limited to the following:

### **a) Early stage of the industry and product development**

Given the early stage of its prescription drug product development, the Company can make no assurance that its research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, the Company, alone or with others, must successfully develop, gain regulatory approval for, and market its future products. The Company currently has no products that have been approved by Health Canada, the FDA, or any similar regulatory authority. To obtain regulatory approvals for its prescription drug product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the prescription drug product candidates are safe for human use and that they demonstrate efficacy.

Many prescription drug product candidates 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. Prescription drug product candidates can 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. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company or its collaborators to abandon commitments to that program. 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 favourable outcomes in later-stage clinical trials, and the Company can make no assurance that any future studies, if undertaken, will yield favourable results.

The early stage of the Company's product development makes it particularly uncertain whether any of its product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of its prescription drug product candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed. If the Company is successful in developing its current and future prescription drug product candidates into approved products, it will still experience many potential obstacles, which would affect its ability to successfully market and commercialize such approved products, such as the need to develop or obtain manufacturing, marketing and distribution capabilities, price pressures from third-party payors, or proposed changes in health care systems. If the Company is unable to successfully market and commercialize any of its products, its financial condition and results of operations may be materially and adversely affected.

The Company can make no assurance that any future studies, if undertaken, will yield favorable results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and the Company cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events or latent defects in the manufactured drug product or the formulation or stability thereof. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their prescription drug product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain Health Canada or FDA approval. If the Company fails to produce positive results in future clinical trials and other programs, the development timeline and regulatory approval and commercialization prospects for the Company's leading prescription drug product candidates, and, correspondingly, its business and financial prospects, would be materially adversely affected.

Preclinical testing and clinical trials for the Company's products may not achieve the desired results. The results of preclinical testing and clinical trials are uncertain. Product approvals are subject to a number of contingencies and may not be obtained in the time expected or at all. The Company's products may not attract a following among patients, retailers and/or providers. The Company expects to face an inherent risk of exposure to product liability claims, regulatory action and litigation if the products it plans to distribute are alleged to have caused loss or injury. There can be no assurance that the Company will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities.

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The Company's business relies on its ability to access, develop, and sell psilocybin. Psilocybin is a controlled substance in many jurisdictions, including in Canada under Schedule III of the Controlled Drugs and Substances Act and in the United States. The Company may face difficulty accessing psilocybin and the public capital markets in Canada as a result of the response of regulators, stock exchanges, and other market participants to the Company's development and sale of a controlled substance. The Company may have limited access to traditional banking services, as well as limited access to debt financing from traditional institutional lenders. The medical efficacy of psilocybin has not been confirmed and requires further study and scientific rigour.

**b) Regulatory risks and uncertainties**

In Canada, certain psychedelic drugs, including psilocybin, are classified as Schedule III drugs under the CDSA and as such, medical and recreational use is illegal under Canadian federal laws. In the United States, certain psychedelic drugs, including psilocybin and psilocin are classified as Schedule I drugs under the CSA and the Controlled Substances Import and Export Act and as such, medical and recreational use is illegal under the U.S. federal laws. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the DEA and obtain DEA approval of the research proposal.

There is no guarantee that psychedelic drugs or psychedelic inspired drugs will ever be approved as medicines in any jurisdiction in which the Company operates. All activities involving such substances by or on behalf of the Company are conducted in accordance with applicable federal, provincial, state and local laws. Further, all facilities engaged with such substances by or on behalf of the Company do so under current licences and permits issued by appropriate federal, provincial and local governmental agencies. While the Company is focused on programs using psychedelic inspired compounds, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates and does not intend to have any such involvement. However, the laws and regulations generally applicable to the industry in which the Company is involved in may change in ways currently unforeseen. Any amendment to or replacement of existing laws or regulations, including the classification or re-classification of the substances the Company is developing or working with, which are matters beyond the Company's control, may cause the Company's business, financial condition, results of operations and prospects to be adversely affected or may cause the Company to incur significant costs in complying with such changes or it may be unable to comply therewith. A violation of any applicable laws and regulations of the jurisdictions in which the Company operates could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings initiated by either government entities in the jurisdictions in which the Company operates, or private citizens or criminal charges.

The loss of the necessary licences and permits for any of the above scheduled drugs could have an adverse effect on the Company's operations.

The psychedelic drug industry is a fairly new industry and the Company cannot predict the impact of the ever evolving compliance regime in respect of this industry. Similarly, the Company cannot predict the time required to secure all appropriate regulatory approvals for future products, or the extent of testing and documentation that may, from time to time, be required by governmental authorities. The impact of compliance regimes, any delays in obtaining, or failure to obtain regulatory approvals may significantly delay or impact the development of markets, its business and products, and sales initiatives and could have a material adverse effect on the business, financial condition and operating results of the Company.

The success of the Company's business is dependent on the reform of controlled substances laws pertaining to psilocybin. If controlled substances laws are not favourably reformed in Canada, the United States, and other global jurisdictions, the commercial opportunity that the Company is pursuing may be highly limited.

The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The FDA, Health Canada, or other similar regulatory authorities have not evaluated claims regarding psilocybin, psilocybin analogues, or other psychedelic compounds. The efficacy of such products have not been confirmed by approved research. There is no assurance that the use of psilocybin, psilocybin analogues, or other psychedelic compounds can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. The Company has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that the Company verified such in clinical trials or that the Company will complete such trials. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.

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#### **c) No assurance of commercial success**

The successful commercialization of the Company's products will depend on many factors, including, the Company's ability to establish and maintain working partnerships with industry participants in order to market its products, the Company's ability to supply a sufficient amount of its products to meet market demand, and the number of competitors within each jurisdiction within which the Company may from time to time be engaged. There can be no assurance that the Company or its industry partners will be successful in their respective efforts to develop and implement, or assist the Company in developing and implementing, a commercialization strategy for the Company's products.

#### **d) Reliance on third parties for clinical development activities**

The Company relies and will continue to rely on third parties to conduct a significant portion of its preclinical and clinical development activities. For example, clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in its relationship with third parties, or if it is unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs will face delays. Further, if any of these third parties fails to perform as the Company expects or if their work fails to meet regulatory requirements, the Company's testing could be delayed, cancelled or rendered ineffective.

#### **e) Risks related to third party relationships**

The Company intends to enter into strategic alliances with third parties that the Company believes will complement or augment its proposed business or will have a beneficial impact on the Company. Strategic alliances could present unforeseen integration obstacles or costs, may not enhance the Company's business, and may involve risks that could adversely affect the Company, including significant amounts of management time that may be diverted from operations in order to pursue and complete such transactions or maintain such strategic alliances. Future strategic alliances could result in the incurrence of additional debt, costs and contingent liabilities, and there can be no assurance that future strategic alliances will achieve, or that the Company's existing strategic alliances will continue to achieve, the expected benefits to the Company's business or that the Company will be able to consummate future strategic alliances on satisfactory terms, or at all. Any of the foregoing could have a material adverse effect on the Company's business, financial condition and results of operations.

In addition to the foregoing, the success of the Company's business will depend, in large part, on the Company's ability to enter into, and maintain collaborative arrangements with various participants in the psychedelic pharmaceutical industry. There can be no assurance that the Company will be able to enter into collaborative arrangements in the future on acceptable terms, if at all. There can be no assurance that such arrangements will be successful, that the parties with which the Company has or may establish arrangements will adequately or successfully perform their obligations under such arrangements, that potential partners will not compete with the Company by seeking or prioritizing alternate, competitor products. The termination or cancellation of any such collaborative arrangement or the failure of the Company and/or the other parties to these arrangements to fulfill their obligations could have a material adverse effect on the Company's business, financial condition and results of operations. In addition, disagreements between the Company and any of its industry partners could lead to delays or time consuming and expensive legal proceedings, which could have a material adverse effect on the Company's business, financial condition and results of operations.

#### **f) Reliance on contract manufacturers**

The Company has limited manufacturing experience and relies on contract manufacturing organizations ("CMOs") to manufacture its prescription drug product candidates for preclinical studies and clinical trials. The Company relies on CMOs for manufacturing, filling, packaging, storing and shipping of drug product in compliance with cGMP regulations applicable to its products. All applicable jurisdictions, including Health Canada, and the FDA, ensure the quality of food, drug products and dietary supplements 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 packing of a drug product. There can be no assurances that CMOs will be able to meet the Company's timetable and requirements. The Company has not contracted with alternate suppliers for drug substance production in the event that the current provider is unable to scale up production, or if it otherwise experiences any other significant problems. If the Company is unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, the Company may be delayed in the development of its prescription drug product candidates. Further, CMOs must operate in compliance with cGMP and ensure that their appropriate permits and licences remain in good standing and failure to do so could result in, among other things, the disruption of product supplies.

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The Company's dependence upon third parties for the manufacture of its products may adversely affect its profit margins and its ability to develop and deliver products on a timely and competitive basis.

**g) Safety and efficacy of products**

Before obtaining marketing approval from regulatory authorities for the sale of the Company's prescription drug product candidates, the Company must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the prescription drug 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. The Company does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its prescription drug product candidates in any jurisdiction. A prescription drug product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of its prescription drug product candidates under development will successfully gain market approval from Health Canada, the FDA, or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any such product can be achieved. As with the results of any statistical sampling, the Company cannot be sure that all side effects of its products may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to such product for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects, or the duration of such studies may not be sufficient to identify when those events may occur. There have been products that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of such products from the market, and the Company's products may be subject to similar risks. The Company might have to withdraw or recall its products from the marketplace. The Company may experience a significant drop in the potential future sales of its products if and when regulatory approvals for such products are obtained, experience harm to its reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of the Company's products, or substantially increase the costs and expenses of commercializing and marketing its products.

**h) Clinical testing and commercializing products**

Before obtaining marketing approval from regulatory authorities for the sale of the Company's prescription drug product candidates, it must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the prescription drug 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. The Company does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its prescription drug product candidates in any jurisdiction. A prescription drug product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of its prescription drug product candidates under development will successfully gain market approval from the FDA, or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from this business segment after investing significant amounts of capital in its development.

The Company cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs will increase if it experiences delays in clinical testing. Significant clinical trial delays could shorten any periods during which the Company may have the 48 exclusive right to commercialize its prescription drug product candidates or allow its competitors to bring products to market before the Company, which would impair the Company's ability to successfully commercialize its prescription drug product candidates and may harm its financial condition, results of operations and prospects.

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The commencement and completion of clinical trials for the Company's prescription drug product candidates may be delayed for a number of reasons, including but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing clinical trials on hold;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of the Company's CMOs to comply with cGMP requirements or latent defects in product quality;
- any changes to the Company's manufacturing process that may be necessary or desired, delays or failure to obtain clinical supply from CMOs of the Company's products necessary to conduct clinical trials;
- prescription drug product candidates demonstrating a lack of safety or efficacy during clinical trials, reports of clinical testing on similar technologies and products raising safety or efficacy concerns;
- clinical investigators not performing the Company's 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 the Company's contract research organizations to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities;
- regulatory authorities or ethics committees finding regulatory violations that require the Company 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 regulatory authorities 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.

The Company's product development costs will increase if it experiences delays in testing or approval or if the Company needs to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and the Company may need to amend study protocols to reflect these changes. Amendments may require the Company to resubmit its study protocols to regulatory authorities 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 the Company's business, financial condition and prospects.

Prior to commencing clinical trials in Canada, the United States, or other jurisdictions, for any prescription drug product candidates developed by the Company, it may be required to have an IND (or equivalent) for each prescription drug product candidate and to file additional INDs prior to initiating any additional clinical trials. The Company believes that the data from its studies will support the filing of additional INDs to enable the Company to undertake additional clinical studies as it has planned. However, submission of an IND (or equivalent) may not result in the FDA (or equivalent authorities) allowing further clinical trials to begin and, once begun, issues may arise that will require the Company to suspend or terminate such clinical trials.

Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the future. Failure to submit or have effective INDs (or equivalent) and commence or continue clinical programs will significantly limit its opportunity to generate revenue.

**i) Completion of clinical trials**

As the Company's prescription drug product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, the Company will need to enroll an increasing number of patients that meet its eligibility criteria. There is significant competition for recruiting patients in clinical trials, and the Company may be unable to enroll the patients it needs to complete clinical trials on a timely basis or at all. The factors that affect the Company's ability to enroll patients are largely uncontrollable and include, but are not limited to, the size and nature of the patient population, eligibility and exclusion criteria for the trial, design of the clinical 49 trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, and the number, availability, location and accessibility of clinical trial sites.

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#### **j) Commercial grade product manufacturing**

The Company's prescription drug products will be manufactured in small quantities for preclinical studies and clinical trials by third party manufacturers. In order to commercialize its product, the Company needs to manufacture commercial quality drug supply for use in registration clinical trials. Most, if not all, of the clinical material used in phase III/pivotal/registration studies must be derived from the defined commercial process including scale, manufacturing site, process controls and batch size. If the Company has not scaled up and validated the commercial production of its product prior to the commencement of pivotal clinical trials, it may have to employ a bridging strategy during the trial to demonstrate equivalency of early-stage material to commercial drug product, or potentially delay the initiation or completion of the trial until drug supply is available. The manufacturing of commercial quality product may have long lead times, may be very expensive and requires significant efforts including, but not limited to, scale-up of production to anticipated commercial scale, process characterization and validation, analytical method validation, identification of critical process parameters and product quality attributes, and multiple process performance and validation runs. If the Company does not have commercial drug supply available when needed for pivotal clinical trials, the Company's regulatory and commercial progress may be delayed, and it may incur increased product development costs. This may have a material adverse effect on the Company's business, financial condition and prospects, and may delay marketing of the product.

#### **k) Nature of regulatory approvals**

The Company's development and commercialization activities and prescription drug product candidates are significantly regulated by a number of governmental entities, including Health Canada, and the FDA. Regulatory approvals are required prior to each clinical trial and the Company may fail to obtain the necessary approvals to commence or continue clinical testing. The Company must comply with regulations concerning the manufacture, testing, safety, effectiveness, labeling, documentation, advertising, and sale of products and prescription drug product candidates and ultimately must obtain regulatory approval before it can commercialize a prescription drug product candidate. The time required to obtain approval by such regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials. Any analysis of data from clinical activities the Company performs is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Even if the Company believes results from its sponsored clinical trials are favorable to support the marketing of its prescription drug product candidates, Health Canada, the FDA, or other regulatory authorities may disagree. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a prescription drug product candidate's clinical development and may vary among jurisdictions.

The Company has not obtained regulatory approval for any prescription drug product candidate and it is possible that none of its existing prescription drug product candidates or any future prescription drug product candidates will ever obtain regulatory approval. The Company could fail to receive regulatory approval for its prescription drug product candidates for many reasons, including, but not limited to failure to demonstrate that a prescription drug product candidate is safe and effective for its proposed indication, failure of clinical trials to meet the level of statistical significance required for approval, failure to demonstrate that a prescription drug product candidate's clinical and other benefits outweigh its safety risks, or deficiencies in the manufacturing processes or the failure of facilities of CMOs with whom the Company contracts for clinical and commercial supplies to pass a pre-approval inspection.

A regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and the Company's commercialization plans, or the Company may decide to abandon the development program. If the Company were to obtain approval, regulatory authorities may approve any of its prescription drug product candidates for fewer or more limited indications than the Company request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a prescription drug product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that prescription drug product candidate. Moreover, depending on any safety issues associated with the Company's prescription drug product candidates that garner approval, Health Canada, the FDA, or other regulatory authorities may impose a risk evaluation and mitigation strategy, thereby imposing certain restrictions on the sale and marketability of such products.

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

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**l) Product viability**

If the Company's psychedelic pharmaceutical products are not perceived to have the effects intended by the end user, the Company's business may suffer. In general, psychedelic pharmaceutical products have minimal long-term data with respect to efficacy, unknown side effects and/or interaction with individual human biochemistry or other supplements or medications. As a result, the Company's psychedelic pharmaceutical products could have certain side effects if not used as directed or if taken by an end user that has certain known or unknown medical conditions.

**m) Limited operating history**

The Company is subject to many risks common to early-stage enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources, history of losses and lack of substantial revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of its relatively early stage of operations. Because the Company has a relatively limited operating history in emerging area of business, you should consider and evaluate its operating prospects in light of the risks and uncertainties frequently encountered by early-stage companies in rapidly evolving markets. These risks may include:

- risks that it may not have sufficient capital to achieve its growth strategy;
- risks that it may not develop its product and service offerings in a manner that enables it to be profitable and meet its customers' requirements;
- risks that its growth strategy may not be successful;
- risks that fluctuations in its operating results will be significant relative to its revenues; and
- risks relating to an evolving regulatory regime.

Historically the Company has financed its operations through equity financing. While the Company generates revenues, these revenues may not be sufficient to support future operations or plans for business development. There is no assurance that the Company will be able to maintain the current level of revenue or access further equity. Due to the fact the Company operates a cannabis-related business certain financing options may not be available to the Company. If the Company is unable to sustain or grow its revenue and not be able to attract further equity financing, the Company may not be able to pay liabilities as they become due and thereby would suffer significant financial damage.

The Company's future growth will depend substantially on its ability to address these and the other risks described in this section. If it does not successfully address these risks, its business may be significantly harmed.

**n) There is no assurance that the Company will turn a profit.**

There is no assurance as to whether the Company will be profitable or pay dividends. The Company has incurred and anticipates that it will continue to incur substantial expenses relating to the development and initial operations of its business. The payment and amount of any future dividends will depend upon, among other things, the results of operations, cash flow, financial condition, and operating and capital requirements. There is no assurance that future dividends will be paid, and, if dividends are paid, there is no assurance with respect to the amount of any such dividends. In the event that any of the Company's investments, or any proceeds thereof, any dividends or distributions therefrom, or any profits or revenues accruing from such investments in the United States were found to be in violation of money laundering legislation or otherwise, such transactions may be viewed as proceeds of crime under one or more of the statutes noted above or any other applicable legislation. This could restrict or otherwise jeopardize the ability of the Company to declare or pay dividends, effect other distributions or subsequently repatriate such funds back to Canada.

**o) The Company may not be able to effectively manage its growth and operations, which could materially and adversely affect its business.**

If the Company implements its business plan as intended, it may in the future experience rapid growth and development in a relatively short period of time. The management of this growth will require, among other things, continued development of financial and management controls, stringent control of costs, the ability to attract and retain qualified management personnel and the training of new personnel. The Company intends to utilize outsourced resources, and hire additional personnel, to manage its expected growth and expansion. Failure to successfully manage its possible growth and development could have a material adverse effect on the Company's business and the value of the Company's common shares.

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**p) The Company may be unable to adequately protect its proprietary and intellectual property rights, particularly in the U.S.**

The Company's ability to compete may depend on the superiority, uniqueness and value of any intellectual property and technology that it may develop. To the extent the Company is able to do so, to protect any proprietary rights, the Company intends to rely on a combination of patent, trademark, copyright and trade secret laws, confidentiality agreements with its employees and third parties, and protective contractual provisions.

Despite these efforts, any of the following occurrences may reduce the value of any of the Company's intellectual property:

- the market for the Company's products and services may depend to a significant extent upon the goodwill associated with its trademarks and trade names, and its ability to register certain of its intellectual property under U.S. federal and state law is impaired by the illegality of cannabis under U.S. federal law;
- patents in the cannabis industry involve complex legal and scientific questions and patent protection may not be available for some or any products; the Company's applications for trademarks and copyrights relating to its business may not be granted and, if granted, may be challenged or invalidated;
- issued patents, trademarks and registered copyrights may not provide the Company with competitive advantages; the Company's efforts to protect its intellectual property rights may not be effective in preventing misappropriation of any its products or intellectual property;
- The Company's efforts may not prevent the development and design by others of products or marketing strategies similar to or competitive with, or superior to those the Company develops;
- another party may assert a blocking patent and the Company would need to either obtain a license or design around the patent in order to continue to offer the contested feature or service in its products; or
- the expiration of patent or other intellectual property protections for any assets owned by the Company could result in significant competition, potentially at any time and without notice, resulting in a significant reduction in sales. The effect of the loss of these protections on the Company and its financial results will depend, among other things, upon the nature of the market and the position of the Issuer's products in the market from time to time, the growth of the market, the complexities and economics of manufacturing a competitive product and regulatory approval requirements but the impact could be material and adverse.

**q) The Company may be forced to litigate to defend its intellectual property rights, or to defend against claims by third parties against the Company relating to intellectual property rights.**

The Company may be forced to litigate to enforce or defend its intellectual property rights, to protect its trade secrets or to determine the validity and scope of other parties' proprietary rights. Any such litigation could be very costly and could distract its management from focusing on operating the business. The existence and/or outcome of any such litigation could harm the business. Further, because the content of much of the Company's intellectual property concerns cannabis and other activities that are not legal in some state jurisdictions or under federal law, the Company may face additional difficulties in defending its intellectual property rights.

**r) The Company may become subject to litigation, including for possible product liability claims, which may have a material adverse effect on the Company's reputation, business, results from operations, and financial condition.**

The Company may be named as a defendant in a lawsuit or regulatory action. The Company may incur uninsured losses for liabilities which arise in the ordinary course of business, or which are unforeseen, including, but not limited to, employment liability and business loss claims. Any such losses could have a material adverse effect on the Company's business, results of operations, sales, cash flow or financial condition.

**s) The Company faces competition from other companies where it will conduct business that may have higher capitalization, more experienced management or may be more mature as a business.**

An increase in the companies competing in this industry could limit the ability of the Company to expand its operations. Current and new competitors may have better capitalization, a longer operating history, more expertise and able to develop higher quality equipment or products, at the same or a lower cost. The Company cannot provide assurances that it will be able to compete successfully against current and future competitors. Competitive pressures faced by the Company could have a material adverse effect on its business, operating results and financial condition.



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**t) If the Company is unable to attract and retain key personnel, it may not be able to compete effectively.**

The Company's success has depended and continues to depend upon its ability to attract and retain key management, including its Chief Executive Officer. The Company will attempt to enhance its management and technical expertise by continuing to recruit qualified individuals who possess desired skills and experience in certain targeted areas. The Company's inability to retain employees and attract and retain sufficient additional employees could have a material adverse effect on its business, results of operations, sales, cash flow or financial condition. Shortages in qualified personnel or the loss of key personnel could adversely affect the financial condition of the Company and results of operations of the business. The loss of any of the Company's senior management could materially adversely affect its ability to execute its business plan and strategy, and the Company may not be able to find adequate replacements on a timely basis, or at all.

**u) Failure to successfully integrate acquired businesses, its products and other assets into the Company, or if integrated, failure to further the business strategy, may result in the Company's inability to realize any benefit from such acquisition.**

The Company expects to grow by acquiring businesses. The consummation and integration of any acquired business, product or other assets into the Company may be complex and time consuming and, if such businesses and assets are not successfully integrated, the Company may not achieve the anticipated benefits, cost-savings or growth opportunities. Furthermore, these acquisitions and other arrangements, even if successfully integrated, may fail to further the Company's business strategy as anticipated, expose the Company to increased competition or other challenges with respect to the Company's products or geographic markets, and expose the Company to additional liabilities associated with an acquired business, technology or other asset or arrangement.

**v) Future offerings and dilution**

If additional funds are raised through issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution. The Company's articles permit the issuance of an unlimited number of common shares, and shareholders will have no pre-emptive rights in connection with such further issuance. The directors of the Company have discretion to determine the price and the terms of issue of further issuances. Moreover, additional common shares will be issued on the exercise of options under the Option Plan and upon the exercise of outstanding Warrants. In addition, from time to time, the Company may enter into transactions to acquire assets or the shares of other companies. These transactions may be financed wholly or partially with debt, which may temporarily increase the Company's debt levels above industry standards. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Company to obtain additional capital and to pursue business opportunities, including potential acquisitions. The Company may require additional financing to fund its operations to the point where it is generating positive cash flows. Negative cash flow may restrict the Company's ability to pursue its business objectives.

The Company continues to sell shares for cash to fund operations, capital expansion, mergers and acquisitions that will dilute the current shareholders.

**w) The Company could be liable for fraudulent or illegal activity by its contractors and consultants resulting in significant financial losses to claims against the Company.**

The Company is exposed to the risk that its independent contractors and consultants may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to the Company that violate government regulations. It is not always possible for the Company to identify and deter misconduct by its contractors and consultants and other third parties, and the precautions taken by the Company to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting the Company 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 the Company, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of the Company's operations, any of which could have a material adverse effect on its business, financial condition and results of operations.

**x) The Company's officers and directors may be engaged in a range of business activities resulting in conflicts of interest.**

Although certain officers and board members of the Company are bound by anti-circumvention agreements limiting their ability to enter into competing and/or conflicting ventures or businesses, the Company may be subject to various potential conflicts of interest because some of its officers and directors may be engaged in a range of business activities. In addition, Company's executive officers and directors may devote time to their outside business interests, so long as such activities do not materially or adversely interfere with their duties to the Company. In some cases, the Company's executive officers and directors may have fiduciary obligations associated with these business interests that interfere with their ability to devote time to the Company's business and affairs and that could adversely affect the Company's operations. These business interests could require significant time and attention of the Company's executive officers and directors.

In addition, the Company may become involved in other transactions which conflict with the interests of its directors and the officers who may from time to time deal with persons, firms, institutions or companies with which the Company may be dealing, or which may be seeking investments similar to those desired by it. The interests of these persons could conflict with those of the Company. In addition, from time to time, these persons may be competing with the Company for available investment opportunities. Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, if such a conflict of interest arises at a meeting of the Company's directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the directors of the Company are required to act honestly, in good faith and in the best interests of the Company.

**y) The Company's contracts may not be legally enforceable in the U.S.**

Because the Company's contracts involve cannabis and other activities that are not legal under U.S. federal law and in some jurisdictions, the Company may face difficulties in enforcing its contracts in U.S. federal and certain state courts.

**z) The market price for the Company's common shares may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond the Company's control.**

The market price for the Company's common shares may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond the Company's control, including the following:

- actual or anticipated fluctuations in the Company's quarterly results of operations;
- recommendations by securities research analysts;
- changes in the economic performance or market valuations of companies in the industry in which the Company operates.
- addition or departure of the Company's executive officers and other key personnel;
- release or expiration of lock-up or other transfer restrictions on outstanding Company common shares;
- sales or perceived sales of additional Company common shares;
- significant acquisitions or business combinations, strategic partnerships, joint ventures or capital commitments by or involving us or the Company's competitors;
- operating and share price performance of other companies that investors deem comparable to the Company; fluctuations to the costs of vital production materials and services;
- changes in global financial markets and global economies and general market conditions, such as interest rates;
- operating and share price performance of other companies that investors deem comparable to the Company or from a lack of market comparable companies;
- news reports relating to trends, concerns, technological or competitive developments, regulatory changes and other related issues in the Company's industry or target markets; and
- regulatory changes in the cannabis industry.

Financial markets have recently experienced significant price and volume fluctuations that have particularly affected the market prices of equity securities of companies and that have often been unrelated to the operating performance, underlying asset values or prospects of such companies. Accordingly, the market price of the Company's common shares may decline even if the Company's 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 might result in impairment losses. 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, the Company's operations could be adversely affected and the trading price of the Company's common shares might be materially adversely affected.

**aa) Currency fluctuations**

The Company's revenues and expenses are expected to be primarily denominated in USD, and therefore may be exposed to significant currency exchange fluctuations. Recent events in the global financial markets have been coupled with increased volatility in the currency markets. Fluctuations in the exchange rate between the USD and the Canadian dollar may have a material adverse effect on the Company's business, financial condition and operating results. The Company may, in the future, establish a program to hedge a portion of its foreign currency exposure with the objective of minimizing the impact of adverse foreign currency exchange movements. However, even if the Company develops a hedging program, there can be no assurance that it will effectively mitigate currency risks.

**bb) Achieving publicly announced milestones**

From time to time, the Company may announce the timing of certain events it expects to occur, such as the anticipated timing of results from clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials may ultimately vary from what is publicly disclosed. See "Commercial Grade Product Manufacturing", "Safety and Efficacy of Products", "Clinical Testing and Commercializing Products", "Completion of Clinical Trials", and "Nature of Regulatory Approvals" as discussed under this heading "Risks and uncertainties" for further disclosure of risks and events that may affect the timing of certain events the Company may announce. The Company undertakes no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by-law. Any variation in the timing of previously announced milestones could have a material adverse effect on the Company's business plan, financial condition or operating results and the trading price of its common shares.

**ADDITIONAL INFORMATION**

Additional information relating to the Company is available on SEDAR+.