



**Cybin Inc.**

Management's Discussion and Analysis  
of Financial Condition and Operating Performance

For the year ended March 31, 2023

Date: June 27, 2023

## Management's Discussion and Analysis

This Management's Discussion and Analysis ("MD&A") has been prepared by management of Cybin Inc. ("Cybin" or the "Company") and should be read in conjunction with Cybin's audited consolidated financial statements and notes as at and for the year ended March 31, 2023 (the "Financial Statements"). This MD&A does not address all of the changes to the Company and its business, such changes are addressed in the Company's most recently filed annual information form (the "AIF") on SEDAR. The Financial Statements have been prepared using International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. All amounts are in Canadian dollars unless otherwise indicated. The Financial Statements may be viewed on the SEDAR profile of Cybin at [www.sedar.com](http://www.sedar.com).

This MD&A contains disclosure related to Cybin occurring up to and including June 27, 2023. Unless otherwise indicated, all amounts in this MD&A are in thousands of Canadian dollars.

Cybin was incorporated under the laws of the Province of British Columbia. Its wholly owned subsidiary, Cybin Corp. was incorporated under the laws of the Province of Ontario. Prior to November 5, 2020, the Company's operations were conducted through Cybin Corp. On November 5, 2020, the Company completed a reverse takeover transaction pursuant to the terms of an amalgamation agreement dated June 26, 2020, as amended on October 21, 2020, among the Company, Cybin Corp. and 2762898 Ontario Inc. ("**SubCo**"), a wholly-owned subsidiary of the Company (the "**Reverse Takeover**"). The Reverse Takeover was completed by way of a "three-cornered" amalgamation pursuant to the provisions of the *Business Corporations Act* (Ontario) whereby Cybin Corp. amalgamated with SubCo to form an amalgamated corporation and a wholly owned subsidiary of the Company. Cybin Corp. is deemed to be the acquirer in the Reverse Takeover. As a result, the consolidated statements of financial position are presented as a continuance of Cybin Corp. and the comparative figures presented are those of Cybin Corp.

## Forward-Looking Statements

Certain statements contained in this MD&A constitute "forward-looking information" and "forward-looking statements". All statements, other than statements of historical fact, contained in this MD&A are forward-looking statements, including, without limitation, statements regarding future financial position, business strategy, budgets, research and development and plans and objectives of management for future operations. Such statements can, in some cases, be identified by the use of forward-looking terminology such as "expect," "likely", "may," "will," "should," "intend," or "anticipate," "potential," "proposed," "estimate" and other similar words, including negative and grammatical variations thereof, or statements that certain events or conditions "may" or "will" happen, or by discussions of strategy. The forward-looking statements included in this MD&A are made only as of the date of this MD&A and the Company assumes no obligation to update or revise them to reflect subsequent information, events or circumstances or otherwise, except as required by applicable securities laws.

Forward-looking statements in this MD&A are not guarantees of future performance and involve assumptions, risks and uncertainties that are difficult to predict. Therefore, actual results may differ materially from what is expressed, implied or forecasted in such forward-looking statements. Management provides forward-looking statements because it believes they provide useful information to readers when considering their investment objectives and cautions readers that the information may not be appropriate for other purposes.

Some of the risks which could affect future results and could cause results to differ materially from those expressed in the forward-looking statements contained herein include:

- novel coronavirus "COVID-19";
- limited operating history;
- achieving publicly announced milestones;
- speculative nature of investment risk;
- early stage of the industry and product development;
- regulatory risks and uncertainties
- risks of operating in European countries;
- "foreign private issuer" status under the U.S. Securities Laws;
- plans for growth;

- limited products;
- limited marketing and sales capabilities;
- no assurance of commercial success;
- no profits or significant revenues;
- reliance on third parties for clinical development activities;
- risks related to third party relationships;
- reliance on contract manufacturers;
- safety and efficacy of products;
- clinical testing and commercializing products;
- completion of clinical trials;
- commercial grade product manufacturing;
- nature of regulatory approvals;
- unfavourable publicity or consumer perception;
- social media;
- biotechnology and pharmaceutical market competition;
- reliance on key executives and scientists;
- employee misconduct;
- business expansion and growth;
- negative results of external clinical trials or studies;
- product liability;
- enforcing contracts;
- product recalls;
- distribution and supply chain interruption;
- difficulty to forecast;
- promoting the brand;
- product viability;
- success of quality control systems;
- reliance on key inputs;
- liability arising from fraudulent or illegal activity;
- operating risk and insurance coverage;
- costs of operating as public company;
- management of growth;
- conflicts of interest;
- foreign operations;
- cybersecurity and privacy risk;
- environmental regulation and risks;
- decriminalisation of psychedelics;
- forward-looking statements may prove to be inaccurate;
- effects of inflation;
- political and economic conditions;
- application and interpretation of tax laws;
- enforcement of civil liabilities;

#### Risks Related to Intellectual Property:

- trademark protection;
- trade secrets;
- patent law reform;
- patent litigation and intellectual property;
- protection of intellectual property;
- third-party licences;

#### Financial and Accounting Risks:

- substantial number of authorized but unissued Common Shares (as defined herein);
- dilution;
- negative cash flow from operating activities;
- additional capital requirements;
- lack of significant product revenue;

- estimates or judgments relating to critical accounting policies;

Risks related to the Common Shares:

- market for the Common Shares;
- significant sales of Common Shares;
- volatile market price for the Common Shares;
- tax issues; and
- no dividends.

Although the forward-looking statements contained in this MD&A are based upon what management currently believes to be reasonable assumptions, the Company cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. In particular, the Company has made assumptions regarding, among other things:

- substantial fluctuation of losses from quarter to quarter and year to year due to numerous external risk factors, and anticipation that we will continue to incur significant losses in the future;
- uncertainty as to the Company's ability to raise additional funding to support operations;
- the Company's ability to access additional funding;
- the fluctuation of foreign exchange rates;
- the duration of COVID-19 and the extent of its economic and social impact;
- the risks associated with the development of the Company's product candidates which are at early stages of development;
- reliance upon industry publications as the Company's primary sources for third-party industry data and forecasts;
- reliance on third parties to plan, conduct and monitor the Company's preclinical studies and clinical trials;
- reliance on third party contract manufacturers to deliver quality clinical and preclinical materials;
- the Company's product candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or may not otherwise produce positive results;
- risks related to filing investigational new drug applications to commence clinical trials and to continue clinical trials if approved;
- the risks of delays and inability to complete clinical trials due to difficulties enrolling patients;
- competition from other biotechnology and pharmaceutical companies;
- the Company's reliance on the capabilities and experience of the Company's key executives and scientists and the resulting loss of any of these individuals;
- the Company's ability to fully realize the benefits of acquisitions;
- the Company's ability to adequately protect the Company's intellectual property and trade secrets;
- the risk of patent-related or other litigation; and
- the risk of unforeseen changes to the laws or regulations in the United States (the "**United States**" or the "**U.S.**"), the United Kingdom (the "**United Kingdom**" or the "**UK**"), Canada, the Netherlands, Ireland and other jurisdictions in which the Company operates.

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 this MD&A under "Risk Factors", other factors not currently viewed as material could cause actual results to differ materially from those described in the forward-looking statements. Although Cybin 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.

### ***Corporate Structure Overview***

The Company is a clinical-stage biopharmaceutical company focused on advancing psychedelic-based therapies, delivery mechanisms, novel compounds and protocols as potential treatments for various psychiatric and neurological conditions. The Company is developing technologies and delivery systems aimed at improving the pharmacokinetics of its psychedelic-based molecules while retaining the therapeutic benefit. These new molecules and delivery systems are expected to be studied through clinical trials to confirm safety and efficacy.

On November 5, 2020, the Company completed a reverse takeover transaction pursuant to the terms of an amalgamation agreement dated June 26, 2020, as amended on October 21, 2020, among the Company, Cybin Corp. and SubCo, a wholly-owned subsidiary of the Company. The Reverse Takeover was completed by way of a “three-cornered” amalgamation pursuant to the provisions of the *Business Corporations Act* (Ontario) whereby Cybin Corp. amalgamated with SubCo to form an amalgamated corporation and a wholly owned subsidiary of the Company.

Immediately prior to the completion of the Reverse Takeover, the Company completed a consolidation of all of its issued and outstanding common shares (the “**Common Shares**”) on the basis of 6.672 old Common Shares into one new Common Share. All Common Share and per Common Share amounts expressed herein reflect the post-consolidation Common Shares.

In connection with the Reverse Takeover, Clarmin Explorations Inc. (“**Clarmin**”) changed its name to “Cybin Inc.” and the Common Shares became listed for trading on the Neo Exchange Inc. (the “**Exchange**”) under the trading symbol “CYBN”. In accordance with IFRS 3, *Business Combinations*, the substance of the Reverse Takeover was a reverse takeover of a non-operating company. The Reverse Takeover does not constitute a business combination as Clarmin did not meet the definition of a business under IFRS 3. As a result, the Reverse Takeover is accounted for as a capital transaction with Cybin being identified as the acquirer and the equity consideration being measured at fair value. The resulting consolidated statement of financial position is presented as a continuation of Cybin Corp. and comparative figures presented in the consolidated financial statements after the Reverse Takeover are those of Cybin Corp.

Prior to completing the Reverse Takeover, and during fiscal 2020, the Company was inactive and evaluating business opportunities.

On July 8, 2021, the Company announced the scale-up of its European operations and research activities with various academic and clinical research organizations, including the transfer of its intellectual property assets to its wholly owned Ireland subsidiary, Cybin IRL Limited (“**Cybin Ireland**”).

On August 5, 2021, the Common Shares commenced trading on the NYSE American LLC stock exchange (the “**NYSE American**”) under the symbol “CYBN”. Concurrent with the commencement of trading on the NYSE American, the Common Shares ceased to be quoted on the OTCQB® Venture Market.

Please refer to “General Development of the Business” in the AIF for additional information on the background and operational highlights of Cybin. The AIF may be viewed under the SEDAR profile of Cybin at [www.sedar.com](http://www.sedar.com).

### ***Business Overview***

Cybin is a clinical-stage biopharmaceutical company on a mission to create safe and effective psychedelic-based therapeutics to address the unmet need for new and innovative treatment options for people who suffer from mental health conditions. Cybin’s goal of revolutionizing mental healthcare is supported by a network of world-class partners

and internationally recognized scientists aimed at progressing proprietary drug discovery platforms, innovative drug delivery systems, and novel formulation approaches and treatment regimens.<sup>1</sup>

Cybin's research and development work focuses on a three-pillar strategy that leverages the Company's core competencies in preclinical innovation and clinical development. This strategy supports the creation of intellectual property ("**IP**") focused on developing the Company's platform technology, the progression of clinical development programs including CYB003, a deuterated psilocybin analog, CYB004, a deuterated version of N, N-dimethyltryptamine ("**DMT**"), CYB005, phenethylamine derivatives, and an expansive list of preclinical molecules to facilitate future drug development opportunities.

Cybin currently has more than 50 pending patent applications across 6 patent families spanning 7 research programs through a combination of internal filings and external licensing agreements.

### ***Advancement of Mental Healthcare***

The Company is conducting research and development of psychedelic therapeutics that aim to address unmet needs in the treatment of mental health conditions. This comprehensive development work is predicated on structural modifications of known tryptamine and phenethylamine derivatives to improve their pharmacokinetic properties while maintaining their respective pharmacology.

Across its extensive research and development programs, Cybin is evaluating a wide array of novel, synthetic psychedelic active pharmaceutical ingredients ("**API**") intended to be delivered through innovative drug delivery systems including orally disintegrating tablets ("**ODT**")<sup>2</sup>, via inhalation, via intravenous ("**IV**"), and intramuscular, or subcutaneous ("**SC**") administration<sup>3</sup>.

The Company intends to apply for regulatory approval for therapies targeting indications such as major depressive disorder ("**MDD**"), alcohol use disorder ("**AUD**"), generalized anxiety disorder ("**GAD**") and potentially other various mental health conditions<sup>4</sup>. The Company is also developing compounds that may have the potential to address neuroinflammation<sup>5</sup>, central nervous system ("**CNS**") disorders, and psychiatric disorders<sup>6</sup>.

Further, over the next 12-month period, the Company will continue to seek to establish strategic partnerships that advance the Company's scientific research and IP for new psychedelic-based compounds and novel delivery mechanisms<sup>7</sup>. The Company will also continue to sponsor select internal and partner-related clinical trials that advance the understanding of safety and efficacy for various psychedelic agents that target mental health conditions<sup>8</sup>.

### ***Stage of Development***

Like most life sciences and pharmaceutical companies, the Company's psychedelic business is focused on research and development and any future revenue will be dependent on a number of factors, including the outcome of the Company's clinical trials and the receipt of all necessary regulatory approvals.

In order to establish its business operations, Cybin intends to leverage the extensive professional network of its management to build working partnerships with (i) existing producers of psychedelic products based in Canada, the United States, the EU and the UK to source the psychedelic pharmaceutical products the Company intends to develop

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<sup>1</sup> This is a forward-looking statement that involves material assumptions by the Company. 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. 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>2</sup> See footnote 1.

<sup>3</sup> See footnote 1.

<sup>4</sup> See footnote 1.

<sup>5</sup> See footnote 1.

<sup>6</sup> See footnote 1.

<sup>7</sup> A material factor and assumption underlying this forward-looking statement is that the Company will be able to successfully negotiate strategic partnerships.

<sup>8</sup> The material factors and assumptions underlying this forward-looking statement are: (a) that the Company will be able to successfully negotiate strategic partnerships; and (b) all necessary approvals for the studies will be obtained. As of the date hereof, the Company and the University of Washington are co-sponsoring a randomized, placebo-controlled clinical trial of psychedelic-assisted psychotherapy with psilocybin for frontline clinicians experiencing Covid-related distress.

and distribute under its specific brand, and (ii) to explore options to facilitate the development and distribution and sale of its specific brand of psychedelic pharmaceutical products.<sup>9</sup>

Prescription drugs are classified and regulated under the federal *Food and Drugs Act* (Canada) (the “**Canadian FDA**”). Labeling, marketing and selling of any prescription drug must comply with the Canadian FDA, including by ensuring that the Company’s products are not packaged or marketed in a manner that is misleading or deceptive to a consumer.

In the United States, foods, drugs and dietary supplements are subject to extensive regulation. The *Federal Food, Drug, and Cosmetic Act* (the “**FFDCA**”) and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacturing, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The Company must ensure that all promotion and marketing, distribution, and labeling of any pharmaceutical products comply with the U.S. regulations, including the FFDCA and the U.S. Food and Drug Administration (the “**FDA**”).

On November 4, 2021, the Company announced that it had been granted a Schedule I manufacturing license from the U.S. Drug Enforcement Administration (“**DEA**”). The DEA license is for the Company’s research lab in the Boston area. The license allows the Company to further become a hub for innovation and drug discovery. Previously, the Company conducted much of its R&D work through globally licensed research organizations in the U.S., Canada, and the UK, and through certain in-house capabilities. With the DEA license, the Company has expanded its internal R&D capabilities to support innovative drug discovery and delivery involving Schedule I compounds.

### ***Non-Revenue Generating Projects***<sup>10</sup>

The Company currently has four significant projects, which have not yet generated revenue:

1. Deuterated Psilocybin Analog Program (CYB003)
2. Deuterated Dimethyltryptamine Program (CYB004)
3. Phenethylamine Derivatives Program (CYB005)
4. Technology Programs

The Company has developed EMBARK, a psychological support model that integrates leading clinical approaches to promote supportive healing with psychedelic medicine. EMBARK’s six clinical domains (**E**xistential-Spiritual, **M**indfulness, **B**ody Aware, **A**ffective-Cognitive, **R**elational, **K**eeping Momentum) represent the broad spectrum of ways in which therapeutic benefits may arise in psychedelic treatment and the equally broad training needed to prepare therapists to support them all. The Company launched its EMBARK training program in June 2021, which prepares facilitators to work within all of these domains, while inviting facilitators to bring in their own therapeutic training and expertise in a flexible, yet structured way. The EMBARK curriculum additionally emphasizes trauma-informed, culturally competent, and ethically rigorous care. On April 12, 2023, the Company announced the launch of EMBARK Open Access, a free online foundational training course for psychedelic facilitation. EMBARK Open Access is the first and only free massive open online course that offers psychedelic facilitation training for healthcare professionals and people interested in offering psychological support.

The following is a description of each program, including a description of the Company’s plan for such programs, the status of the objectives related to the Company’s plan for such program and anticipated expenditures to advance the program to the next stage of pipeline development.

### **Deuterated Psilocybin Analog Program (CYB003)**

The Company has been investigating the development of short-acting tryptamines with the aim of creating clinical development candidates, utilizing (i) the chemical modification of tryptamine derivatives through the selective substitution of hydrogen atoms with deuterium (i.e. deuteration); and (ii) the combination of such deuterated

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<sup>9</sup> At this time the Company has not entered into commercial supply agreements and has no control over price or conditions. The Company’s assumption is that it will be able to enter into agreements at such a time when there will be sufficient competition in the market which will render prices reasonable.

<sup>10</sup> All quarter references in this section are based on calendar year-end.

tryptamine derivative molecules with selected drug delivery methods, including but not limited to oral, inhalation methods, IV and intramuscular delivery.

The Company's lead program, CYB003, is an orally delivered deuterated psilocybin analog that aims to address the limitations of oral psilocybin, including side effects, scalability and accessibility of treatment.

In preclinical studies, CYB003 demonstrated several advantages compared to oral psilocybin, including faster onset of action, shorter duration of effect, less variability in plasma levels, and improved brain penetration. These preclinical results could potentially translate into therapeutic benefits, such as shorter treatment duration, more predictable dosing, lower doses to achieve efficacy, and fewer side effects for patients.

The Company completed its CYB003 Investigational New Drug ("**IND**")-enabling preclinical studies and Chemistry, Manufacturing and Control ("**CMC**") development, including the production of clinical materials required for clinical trials, in the second quarter of calendar 2022. In the same period, the Company submitted an IND application to the FDA and received a "may proceed letter" and IND application clearance from the FDA as well as Institutional Review Board (the "**IRB**") approval in the U.S. to commence its first-in-human Phase 1/2a study of CYB003 in participants with moderate to severe MDD. The Company has engaged Clinilabs Drug Development Corporation ("**Clinilabs**"), a full-service contract research organization with deep expertise in central nervous system drug development, to carry out the Phase 1/2a clinical trial of CYB003. On August 30, 2022, the Company announced that the first two participants have been dosed in the Phase 1/2a study.

On February 28, 2023, the Company announced positive interim safety and pharmacokinetics and pharmacodynamics data from the Phase 1/2a study of CYB003. Interim findings showed that CYB003 exhibited rapid, short-acting effects, low variability in plasma levels, and achieved a psychedelic effect at low doses. At the 8mg and 10mg dose levels, participants reported robust and meaningful psychedelic effects, confirming a complete mystical experience was achieved. All doses evaluated (single oral doses of CYB003 up to 10mg) were well-tolerated with no serious adverse events reported. As of February 28, 2023, dosing in the Phase 1 portion of the study has been completed and dosing is ongoing in the Phase 2a portion.

#### ***About the CYB003 Phase 1/2a Clinical Trial***

The Phase 1/2a trial is a randomized, double-blind, placebo-controlled study evaluating CYB003 in participants with moderate to severe MDD and in healthy volunteers. Per a protocol amendment to the initial Phase 1/2a study design that was announced on February 28, 2023, the study introduced healthy volunteers for the lower (sub-therapeutic) dose cohorts and added a bioequivalence and food effect cohort to facilitate the transition to pivotal studies. Healthy volunteers receive two administrations (placebo/active and active/active) one week apart, and measures of psychedelic effect are assessed after each dose. Participants with MDD receive two administrations (placebo/active and active/active) three weeks apart and response/remission are assessed three weeks after each dose. MDD participants in the trial that are currently being treated with antidepressants will be allowed to remain on their antidepressant medication.

The study will investigate the safety, tolerability, pharmacokinetics ("**PK**") and pharmacodynamics ("**PD**"), and psychedelic effect of ascending oral doses of CYB003. In participants with MDD, the trial will also assess rapid onset of antidepressant effect on the day of dosing, using the Montgomery-Asberg Depression Rating Scale ("**MADRS**"), and evaluate the incremental benefit of a second dose of CYB003 when administered at Week 3. An optional period of assessment will help determine the durability of treatment effect out to 12 weeks. The study is listed on ClinicalTrials.gov under Identifier: NCT05385783.

The Company spent approximately \$8,445 on the Deuterated Psilocybin Analog Program during the financial year ended March 31, 2023. The Company additionally spent \$1,410 related to licensing agreements for this program (see "Intellectual Property").

As the Company continues to progress through the CYB003 program, additional milestones related to the Phase 1/2a clinical trial have been identified. The Company intends to:



- provide topline data readout from the Phase 1/2a study in Q3/Q4 2023<sup>11,12</sup>.
- complete FDA submission of CYB003 Phase 1/2a data for end of phase 2 meeting in Q4 2023<sup>13</sup>.

The Company spent approximately \$2,527<sup>14</sup> to receive its initial pharmacokinetic and safety readout in February 2023. The Company expects to spend approximately \$6,226<sup>15</sup> to provide topline data readout from the Phase 1/2a study by late Q3 2023<sup>16</sup>, of which approximately \$1,392 was spent during the financial year ended March 31, 2023. The Company intends to continue funding the Deuterated Psilocybin Analog (CYB003) Program.

The Company intends to complete future clinical trials for this program in the U.S., Canada, and/or Europe.

#### **Deuterated Dimethyltryptamine Program (CYB004)**

The Company's Deuterated Dimethyltryptamine Program is focused on the development of CYB004, a deuterated version of DMT. DMT has been shown to exert its psychedelic effects by activating the 5-HT<sub>2A</sub> receptor. In its regular form, DMT is an unstable molecule rapidly metabolized in the body, which significantly reduces its bioavailability. By maximizing CYB004 as a deuterated molecule and improving upon the bioavailability of DMT, CYB004 has the potential to overcome existing limitations of DMT and may offer less invasive and more convenient dosing methods compared to IV DMT. Cybin is currently developing CYB004 for the potential treatment of GAD, with or without MDD. CYB004 is secured by a U.S. composition of matter patent with protection through 2041. The patent covers a range of deuteration forms of DMT and protects CYB004 as a putative new chemical entity.

In preclinical studies, inhaled CYB004 demonstrated significant advantages over both IV DMT and inhaled DMT, including longer duration of action, and improved bioavailability. The study also demonstrated that inhaled CYB004 showed a similar onset of effect and dose profile to IV DMT. These data may support the potential for inhalation as a viable and well-controlled delivery system of psychedelic-based therapeutics.

On June 7, 2022, the Company announced it had entered into an agreement to acquire a Phase 1 DMT study (the "**Asset Acquisition**") from Entheon Biomedical Corp. ("**Entheon**") to accelerate the clinical development path for CYB004. On July 11, 2022, the Company announced that the Asset Acquisition was completed. The Phase 1 study, previously identified as EBRX-101 and now named CYB004-E, is being conducted in the Netherlands. Entheon acted as external consultants to the Company for approximately 10 months after the Asset Acquisition.

On January 12, 2023, the Company announced that it has selected GAD with or without MDD as the target indication for its proprietary deuterated DMT molecule, CYB004.

#### ***About the Phase 1 CYB004-E DMT Study***

The Phase 1 trial is a three-part study evaluating the safety, pharmacokinetics, and pharmacodynamics of escalating doses of DMT and CYB004 in healthy volunteers. The three-part study design was established in a protocol amendment to the initial study design, allowing the Company to commence first-in-human dosing of CYB004 sooner than initially planned. The study is expected to provide essential safety and dosing optimization data to inform the

<sup>11</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>12</sup> The Company has updated this milestone. The Company had previously expected it would complete this milestone in late Q3 2023. The Company now expects to receive the initial topline data readout in late Q3 2023, with the balance of the data being available in Q4 2023 based upon the current progress to date. Anticipated spending and timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company.

<sup>13</sup> See footnote 11. The advancement of the Company's Deuterated Psilocybin Analog Program (CYB003) program beyond providing a topline data readout from the Phase 1/2a study in Q3/Q4 2023 is contingent on the Company's ability to continue raising capital under its current and future financing arrangements. No assurances can be given that the Company will be able to raise the additional capital that it may require for its anticipated future development. See "*Risk Factors*" for further information.

<sup>14</sup> Reflects spending during the financial year ended March 31, 2023. The Company had previously estimated that its actual and expected spend up to February 2023, for this program would be \$3,192. Anticipated spending and timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company.

<sup>15</sup> Reflects actual spend during the period from March 1, 2023 to March 31, 2023 and expected spend during the period from April 1, 2023 until the achievement of topline data readout from the Phase 1/2a study in Q3/Q4 2023. The expected spend assumes the advancement of the Company's CYB003 program beyond providing a topline data readout from the Phase 1/2a study in late Q3 2023, which advancement is contingent on the Company's ability to continue raising capital under its current and future financing arrangements.

<sup>16</sup> See footnote 11.

clinical path forward for CYB004. The CYB004-E study is being conducted at the Centre for Human Drug Research in the Netherlands and is one of the largest Phase 1 DMT clinical trials to date.

On November 10, 2022, the Company announced that its CYB004-E Phase 1 trial evaluating IV DMT completed dosing for four out of five participant cohorts and that the Safety Review Committee had confirmed no safety or toxicity issues.

On February 1, 2023, the Company announced that it had received approval from an independent ethics committee in the Netherlands to initiate first-in-human dosing of CYB004 through a protocol amendment to its ongoing Phase 1 CYB004-E study.

On February 28, 2023, the Company announced a protocol amendment to the initial Phase 1 study design that would allow the Company to initiate first-in-human dosing of CYB004 sooner than initially planned. Per the protocol amendment, Cybin established a three-part study to include Part A (IV DMT infusion), Part B (IV DMT bolus + infusion) and Part C (IV CYB004 bolus + infusion) in healthy volunteers. The Company was able to rely upon completed preclinical data to gain regulatory authorization to add CYB004 to the CYB004-E DMT Study. The Company also announced confirmatory data from Part A, the single ascending dose portion of the CYB004-E study, which assessed a continuous IV DMT infusion. The Part A data showed a dose-proportional increase in exposure and dose-related increase in behavioral measures of subjective psychedelic experience with IV DMT. IV DMT was also well-tolerated with no safety issues and no serious adverse events within the dose range evaluated.

On May 9, 2023, the Company announced that it had completed dosing for the last subject in Part B of the Phase 1 CYB004-E trial.

On May 24, 2023, the Company announced that it had initiated first-in-human dosing of CYB004 in Part C of the Phase 1 CYB004-E trial.

The Company spent approximately \$7,770 on its Deuterated Dimethyltryptamine Program during the financial year ended March 31, 2023.

As the Company continues to progress its Deuterated Dimethyltryptamine Program, additional milestones related to its clinical development have been identified<sup>17</sup>. The Company intends to:

- provide topline data from the Phase 1 CYB004-E trial in Q3/Q4 2023<sup>18</sup>.
- complete FDA IND submission in Q1 2024<sup>19</sup>.

The Company expects to spend approximately \$10,906 to complete FDA IND submission for CYB004 by Q1 2024 and \$4,278<sup>20</sup> to provide topline data from the Phase 1 CYB004-E trial in Q3 2023. The Company intends to continue funding the Deuterated Dimethyltryptamine (CYB004) Program.

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<sup>17</sup>See footnote 11. The Company is prioritizing its progression of its Deuterated Psilocybin Analog Program (CYB003). The advancement of the Company's Deuterated Dimethyltryptamine Program (CYB004) is contingent on the Company's ability to continue raising capital under its current and future financing arrangements. No assurances can be given that the Company will be able to raise the additional capital that it may require for its anticipated future development. See "Risk Factors" for further information.

<sup>18</sup>The Company has updated this milestone. The Company had previously expected it would complete this milestone in late Q3 2023. The Company now expects to receive the initial topline data readout in late Q3 2023, with the balance of the data being available in Q4 2023 based upon the current progress to date. Anticipated spending and timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. See footnote 11.

<sup>19</sup>The Company has updated this milestone. The Company had previously expected it would complete the IND-enabling preclinical studies of CYB004 by December 31, 2023. As noted in the press release on February 28, 2023 this milestone is no longer required to advance the program. The Company has updated the milestone to submit clinical data for regulatory submission in Q1 2024. The Company previously disclosed expected spending up to December 31, 2023 for this milestone would be \$9,518. Anticipated timing and spending regarding drug development is 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>20</sup>The Company has updated this milestone. The Company had previously estimated that its spending up to the first half of 2023 to advance the Phase 1 CYB004-E trial would be \$3,366. The Company expects to provide topline data from the Phase 1 CYB004-E trial in Q3 2023. Anticipated timing and spending regarding drug development is 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.

## **Phenethylamine Derivatives Program (CYB005)**

The Company's Phenethylamine Derivatives Program (CYB005) is focused on the development of therapeutic phenethylamine derivatives. Multiple phenethylamines have been shown to have psychedelic properties and several, such as MDMA, have shown promise as therapeutics. Cybin's proprietary approach to phenethylamines modification with novel chemistry, proprietary formulations and directed delivery systems has yielded a number of novel, IP-protected leads with significant therapeutic potential. Several compounds are now being further studied both in vitro and in vivo for selection of the best development candidates, including evaluating the benefits of sub-psychedelic, chronic dosing. The Company is investigating the effects of phenethylamine derivatives on neuroplasticity, and for the potential treatment of psychiatric disorders, neuroinflammation and other neurological conditions.<sup>21</sup>

In order to assess the feasibility and viability of these phenethylamine derivatives entering clinical studies, the Company has and will continue to contract with reputable and licensed third-party vendors to undertake extensive preclinical characterization of target molecules on the Company's behalf. These activities include, but are not limited to: the synthesis of such molecules as API at laboratory scale, the development and optimization of production processes for such APIs, the development of stable formulations utilizing these APIs, the development and validation of analytical methods for such formulations, the scale up of API production processes beyond laboratory scale to deliver GLP and GMP material suitable for entry into animal and human studies, studies of the stability of such formulations suitable for human studies, the development of Chemistry, Manufacturing and Controls to meet cGMP.

In addition, utilizing the expertise of selected third parties, the Company intends to oversee the study of the pharmacokinetic (PK) profiles of its formulations in a number of animal models and the completion of Absorption, Distribution, Metabolism, and Excretion ("ADME") profiles. Further, the Company's licensed third party vendors will be responsible for completing a range of additional preclinical programs including, but not limited to, dose-ranging studies in multiple animal species, toxicity studies in multiple animal species, genotoxicity studies, along with neuropharmacological, pulmonary, and cardiovascular profiling, before the final selection of drug candidates for entry into human trials.

The Company intends to complete these studies, and collect further relevant safety and toxicity data, prior to the filing for any IND application with the FDA, a CTA with Health Canada, or other similar application with regulatory bodies in other jurisdictions.

The Company spent approximately \$782 on its preclinical Phenethylamine Derivatives Program during the financial year ended March 31, 2023.

The Company is currently identifying a viable drug candidate and completing its assessment of the potential path forward for this candidate, including whether it will be developed internally or by way of potential third party partners. The Company anticipates that its phenethylamine program may deliver a drug candidate suitable for entry into clinical studies by the end of calendar 2023<sup>22</sup>.

The Company expects to spend approximately \$1,283<sup>23</sup> to complete preclinical development of a phenethylamine drug candidate by September 30, 2023. The Company intends to continue funding the Phenethylamine Derivatives Program (CYB005) Program.

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<sup>21</sup> This statement is based on the following material factors and assumptions: (a) the Company assumes it will enter into a contract with a licensed third-party vendor to undertake extensive preclinical characterization of target molecules on the Company's behalf; (b) the Company anticipates to complete a number of animal models and the completion of ADME profiles; (c) the Company assumes to enter into third party agreements in order to complete a range of additional preclinical programs including but not limited to dose-ranging studies in multiple animal species, toxicity studies in multiple animal species, genotoxicity studies, teratogenicity studies, along with neuropharmacological, pulmonary, and cardiovascular profiling before the final selection of drug candidates for entry into human trials; and (d) obtain an IND and/or a CTA to enter into clinical trials. 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.

<sup>22</sup> See footnote 11. The Company is prioritizing its progression of its Deuterated Psilocybin Analog Program (CYB003). The advancement of the Company's Phenethylamine Derivatives Program (CYB005) is contingent on the Company's ability to continue raising capital under its current and future financing arrangements. No assurances can be given that the Company will be able to raise the additional capital that it may require for its anticipated future development. See "Risk Factors" for further information.

<sup>23</sup> See footnote 21.

## **Technology Programs**

### ***Digital Therapy Platform***

The Company has been working on the creation of a patient digital therapy platform (the “**Digital Platform**”). The Digital Platform is envisioned to help patients undergoing psychedelic therapies to memorialize the learning from their treatment sessions and to assist with the integration of such learnings into the patient’s psychotherapy program.

The Company’s digital therapy platform technology is designed to better enable the evaluation of patient outcomes through a highly secure, patient-centered data analytics platform for better pre- and post-psychedelic treatments. The digital therapy platform is proprietary to Cybin and the subject of one of the Company’s patent applications.

Proof-of-concept testing for the Company's Digital Platform was completed in Q2 2022. The Company is currently evaluating paths forward for its Digital Platform program.

### ***Kernel Collaboration***

On January 11, 2021, the Company announced that it entered into an agreement with HI, LLC dba Kernel (“**Kernel**”) that will enable the Company to use the Kernel Flow technology (“**Flow**”) to potentially measure neural activity during psychedelic therapy.

On October 26, 2021, the Company announced that the FDA had authorized an IND application to proceed with a Cybin-sponsored feasibility study using Flow to measure ketamine’s psychedelic effect on cerebral cortex hemodynamics. On January 11, 2022, the Company announced that the IRB had approved the feasibility study. On May 9, 2022, the Company and Kernel announced results from the piloting of the feasibility study. The preliminary data confirmed Flow's ability to successfully measure neuro-effect of ketamine over 10 days.<sup>24</sup> The Company completed its feasibility study sponsorship utilizing Flow in Q3 2022.

On January 18, 2023, the Company announced promising results from the completed feasibility study, evaluating Flow's wearable technology to measure ketamine's psychedelic effect on cerebral cortex hemodynamics. Key findings from the study provided proof-of-principle for Flow as a portable functional system that provides real-time measurements of changes in blood oxygenation in the brain associated with neural activity. The study demonstrated ketamine-induced changes to functional brain biomarkers associated with potential therapeutic effects, including changes in cortical function associated with psychedelic experiences. Additionally, Flow demonstrated reliable measurements of pulse rate (“PR”) and pulse rate variability (“PRV”), therefore eliminating the need for external cardiac activity sensors in future studies. The study also observed physiological measures of the effects of ketamine, including increased PR, decreased PRV, increased absolute concentrations of oxy-hemoglobin and decreased deoxyhemoglobin, and elevated electrodermal activity.

Results from the study are intended to inform the next steps forward for this program.

### ***About the Phase 1 Kernel Flow Feasibility Study***

The feasibility study was a single-blind, placebo-controlled, non-randomized design with participants completing study visits roughly once a week for four weeks. The four study visits were always conducted in the same order: a screening visit, two dosing visits, and a follow-up phone call. Dosing visits were always placebo (saline, 0.9% NaCl) first and ketamine second, with the ketamine visit occurring one week ( $7.1 \pm 0.5$  days, mean  $\pm$  standard deviation) after the saline visit. Ketamine and saline were administered via bolus intramuscular injection (deltoid muscle). Ketamine dosing was based on participant weight with a target of 0.75 mg/kg, up to the maximum dose of 60 mg. Two participants were administered the maximum dose. Participants included 15 healthy individuals who met eligibility criteria and consented to participation in the study. There were eight females and seven males, all 24-48 years old.

The main objective of the feasibility study was to evaluate a participant’s experience wearing Flow while in an altered state of consciousness following the administration of ketamine.

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<sup>24</sup> Preliminary data from the piloting suggested that ketamine-induced changes in functional connectivity persisted for several days after administration. Flow successfully measured the neuro-effect of ketamine over 11 days (baseline at Days 1-5, dosing at Day 6, follow-up at Days 7-11), and confirmed changes in functional connectivity that are consistent with current scientific research (Scheidegger *et al* 2012; Zacharias *et al* 2019; Li *et al* 2022). The piloting was conducted to ensure the efficiency of the feasibility study design. Participants in the pilot received either a low dose of ketamine and/or a placebo while wearing the Flow headset.

As part of the Company's sponsorship of the feasibility study, the Company will retain an exclusive interest in any innovations that are discovered or developed through its independent analysis of the study findings.

The Company spent approximately \$493 on its technology programs during the financial year ended March 31, 2023.

### **Relationships with Third Parties**

The Company's research and development of its psychedelic pharmaceutical products is conducted by way of licensed partners. The Company also intends to sponsor clinical and other studies at various clinical trial sites.

#### ***University of Washington***

As of the date of this MD&A, the Company and the University of Washington are co-sponsoring a randomized, placebo-controlled clinical trial of psychedelic-assisted psychotherapy with psilocybin, utilizing the Company's EMBARK psychological support model, for frontline clinicians experiencing COVID-19 related distress.

#### ***Greenbrook TMS***

On July 6, 2021, the Company entered into a collaboration agreement with Greenbrook TMS to establish mental health centers of excellence for the purpose of facilitating research and development of innovative psychedelic compound-based therapeutics for patients suffering from depression.

#### ***Clinilabs Drug Development Corporation***

On April 21, 2022, the Company announced that it had partnered with Clinilabs, a global, full-service contract research organization with deep expertise in central nervous system drug development, to carry out the Company's Phase 1/2a clinical trial of CYB003, its proprietary deuterated psilocybin analog. CYB003 is the first psilocybin analog to be evaluated in Phase 1/2a development for the treatment of MDD.

#### ***Entheon Biomedical Corp.***

On July 11, 2022, the Company completed the acquisition of a Phase 1 DMT study from Entheon. As part of the Asset Acquisition, Entheon assigned its rights under the Master Services Agreement between Entheon and Centre For Human Drug Research ("CHDR") to the Company. The Company now maintains a direct contractual relationship with CHDR to conduct the CYB004-E trial. CHDR is an independent institute in the Netherlands specializing in innovative early-stage clinical drug research.

#### ***Mindset Pharma Inc.***

On September 27, 2022, the Company entered into an agreement, as amended, with Mindset Pharma Inc. ("Mindset") to acquire an exclusive license to an extensive targeted class of tryptamine-based molecules. The agreement includes an initial license fee payment by Cybin to Mindset of US\$500 as well as additional clinical development milestone payments of up to US\$9,500, with the first milestone payment, in the amount of US\$500, payable upon completion of a Phase 1 clinical trial. At the sole discretion of Cybin, the milestones may be paid in cash or in Common Shares, or a combination thereof, subject to the approval of the Neo Exchange Inc. There is no assurance that the aforementioned milestones will be met. The agreement also contemplates a sales royalty of approximately 2% for all commercialized licensed products within the scope of the agreement, which is customary for drug licensing agreements of this nature.

#### ***Other Third-Party Partners***

The Company has established contractual sources of synthetic GMP (as defined below) and non-GMP raw materials to support its development operations through licensed third-party suppliers located in Canada, the United States, the UK and Europe. Such raw materials are expected to be, in general, readily available and in adequate supply to meet the Company's need for development quantities, or custom manufactured on the Company's behalf.<sup>25</sup> The prices of research quantities of psilocybin and novel psychedelic compounds are generally higher than commercial supply prices at significantly larger scale and the Company, therefore, expects its supply prices to reduce over time. Development and production of the Company's proprietary novel compounds is performed under confidential contractual agreements.

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<sup>25</sup> At this time the Company has not entered into commercial supply agreements and has no control over price or conditions. The Company has assumed that it will be able to enter into commercial supply agreements at such a time when there will be sufficient competition in the market which will render prices reasonable.

The Company has conducted due diligence on each such third party, including but not limited to the review of necessary licences and the regulatory framework enacted in the jurisdiction of operation.

The allocation of capital towards the Company's ongoing projects and programs is largely dependent on the success, or difficulties encountered, in any particular portion of the process and therefore the time involved in completing it; in turn the time and costs associated with completing each step are highly dependent on the incremental results of each step and the results of other programs, and the Company's need to be flexible to rapidly reallocate capital to projects whose results show the greatest potential. As such, it is difficult for the Company to anticipate the timing and costs associated with taking the projects to their next planned stage, and the Company cannot make assurances that the foregoing estimates will prove to be accurate, as actual results and future events could differ materially from those anticipated. Accordingly, investors are cautioned not to put undue reliance on the foregoing estimates.

Moreover, identifying the timing and costs of such projects beyond their immediate next steps go to the core differentiating factors with respect to the Company and its competitors. The disclosure of prospective costs and timing other than as already disclosed by the Company would negatively impact shareholder value and undermine the Company's proprietary technology. In keeping with pharmaceutical industry practice, it is the Company's policy to disclose these details in conjunction with its financial statements, and to publicly disclose published patent applications, published scientific papers, scientific symposia and the attainment of key milestones only. In addition, the premature disclosure of proprietary data would have a material and adverse effect on the Company's patent and other intellectual property rights and could result in the breach of confidentiality obligations.

The material factors or assumptions used to develop the estimated costs disclosed above are included in the "Cautionary Note Regarding Forward-Looking Information" section above. The actual amount that the Company spends in connection with each of the intended uses of proceeds will depend on a number of factors, including those listed under "Risk Factors" in this MD&A or unforeseen events.

Other than as described in the AIF and herein, to the knowledge of management, there are no other particular significant events or milestones that must occur for the Company's business objectives in the next 12 months to be accomplished. However, there is no guarantee that the Company will meet its business objectives or milestones described above within the specific time periods, within the estimated costs or at all. The Company may, for sound business reasons, reallocate its time or capital resources, or both, differently than as described above.

The Company has negative cash flow from operating activities and has historically incurred net losses. To the extent that the Company has negative operating cash flows in future periods, it may need to deploy a portion of its existing working capital to fund such negative cash flows. The Company will be required to raise additional funds through the issuance of additional equity securities, through loan financing, or other means, such as through partnerships with other companies and research and development reimbursements. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favourable to the Company as those previously obtained.

Certain COVID-19 related risks could delay or slow the implementation of the planned objectives resulting in additional costs for the Company to achieve its business objectives. The extent to which COVID-19 may impact the Company business activities will depend on future developments, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, business disruptions, and the effectiveness of actions taken in Canada, the United States, and other countries to contain and treat the disease. As these events are highly uncertain and the Company cannot determine their potential impact on operations at this time. The COVID-19 pandemic may negatively impact the Company's business through disruption of supply and manufacturing, which would influence the amount and timing of planned expenditure. For example, prolonged disruptions in the supply of goods and services relied on by the Company to develop its products or restrictions resulting from government regulations that impact the Company ability to conduct its studies and clinic trials, may adversely impact the Company's business.

## Intellectual Property

Cybin has title to one granted US patent related to the Company's investigational deuterated DMT compound CYB004. The patent covers composition of matter and protects the CYB004 drug substance, a putative new chemical entity.

	Patent Number	Jurisdiction of Filing	Description
1	11,242,318	United States	Deuterated Tryptamine Derivatives And Methods Of Use

In addition, Cybin has title to eight provisional patent applications, eight US non-provisional patent applications, thirty two national (non-US) patent applications, and ten Patent Cooperation Treaty ("PCT") applications, including claims directed to compositions of matter and methods of use in support of its research and development and preclinical and clinical trial programs.

	Patent Application Number	Jurisdiction of Filing	Status	Description
1	PCT/EP2022/069109	Ireland	Pending	Integrated Data Collection Devices for Use in Various Therapeutic and Wellness Applications
2	17/564,707	United States	Pending	Deuterated Tryptamine Derivatives and Methods of Use
3	PCT/EP2022/056991	Ireland	Pending	Psilocybin Analogs, Salts, Compositions, and Methods of Use
4	PCT/EP2022/058574	Ireland	Pending	Combination Drug Therapies
5	PCT/EP2022/063269	Ireland	Pending	Formulations of Psilocybin
6	63/402,650	United States	Pending	Tryptamine Compounds, Compositions, and Methods of Use
7	PCT/EP2022/076073	Ireland	Pending	Formulations Of Psilocybin Analogs and Methods of Use
8	17/974,007	United States	Pending	Deuterated Tryptamine Derivatives and Methods of Use
9	63/420,265	United States	Pending	Phenethylamine Compounds, Compositions, and Methods of Use
10	18/056,958	United States	Pending	Deuterated Tryptamine Derivatives and Methods of Use
11	17/999,310	United States	Pending	Deuterated Tryptamine Derivatives and Methods of Use
12	63/384,704	United States	Pending	Tryptamine Compositions and Methods
13	63/386,375	United States	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
14	PCT/EP2023/050702	Ireland	Pending	Tryptamine Compositions and Methods
15	PCT/EP2023/053744	Ireland	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
16	PCT/EP2023/053752	Ireland	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
17	18/041,731	United States	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
18	18/041,728	United States	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
19	18/172,691	United States	Pending	Deuterated Tryptamine Derivatives and Methods of Use
20	63/487,078	United States	Pending	Methods of Treating Disorders
21	18/027,810	United States	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods
22	PCT/EP2023/057939	Ireland	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods
23	PCT/EP2023/058107	Ireland	Pending	Combination Drug Therapies
24	63/464,265	United States	Pending	Injectable Pharmaceutical Formulations
25	63/507,059	United States	Pending	Companion Animal Treatments
26	63/507,062	United States	Pending	Injectable Pharmaceutical Formulations

	Patent Application Number	Jurisdiction of Filing	Status	Description
27	793553	New Zealand	Pending	Deuterated Tryptamine Derivatives and Methods of Use
28	297492	Israel	Pending	Deuterated Tryptamine Derivatives and Methods of Use
29	3177454	Canada	Pending	Deuterated Tryptamine Derivatives and Methods of Use
30	NC2022/0016662	Colombia	Pending	Deuterated Tryptamine Derivatives and Methods of Use
31	MX/a/2022/014605	Mexico	Pending	Deuterated Tryptamine Derivatives and Methods of Use
32	202203191	Chile	Pending	Deuterated Tryptamine Derivatives and Methods of Use
33	10-2022-7040243	Republic of Korea	Pending	Deuterated Tryptamine Derivatives and Methods of Use
34	EP21808464.8	European Patent Office	Pending	Deuterated Tryptamine Derivatives and Methods of Use
35	202180036163.3	China	Pending	Deuterated Tryptamine Derivatives and Methods of Use
36	1120220235658	Brazil	Pending	Deuterated Tryptamine Derivatives and Methods of Use
37	2021276656	Australia	Pending	Deuterated Tryptamine Derivatives and Methods of Use
38	11202254530T	Singapore	Pending	Deuterated Tryptamine Derivatives and Methods of Use
39	202213256	South Africa	Pending	Deuterated Tryptamine Derivatives and Methods of Use
40	2201007493	Thailand	Pending	Deuterated Tryptamine Derivatives and Methods of Use
41	1-2022-553135	Philippines	Pending	Deuterated Tryptamine Derivatives and Methods of Use
42	202227065770	India	Pending	Deuterated Tryptamine Derivatives and Methods of Use
43	2022-571175	Japan	Pending	Deuterated Tryptamine Derivatives and Methods of Use
44	3186357	Canada	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
45	10-2023-7003815	Korea	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
46	2021327136	Australia	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
47	2023-512063	Japan	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
48	21766581.9	European Patent Office	Pending	Therapeutic Phenethylamine Compositions and Methods of Use
49	3186359	Canada	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
50	10-2023-7006128	Korea	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
51	2021328671	Australia	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
52	2023-512107	Japan	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
53	21763068.0	European Patent Office	Pending	Phenethylamine Derivatives, Compositions, and Methods of Use
54	21786852.0	European Patent Office	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods
55	10-2023-7007858	Korea	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods
56	2021354006	Australia	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods
57	2023-519831	Japan	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods
58	3194558	Canada	Pending	Methods For Delivery of Psychedelic Medications By Inhalation and Systems For Performing the Methods

Cybin's patent applications cover a wide range of novel psychedelic compounds from different classes, including those with targeted structural modifications for improved pharmacokinetic characteristics and safety profiles without altering their receptor binding. The patent applications also cover novel drug delivery platforms for administration of the psychedelic drugs with faster onset of action, higher bioavailability by way of bypassing liver metabolism, more controlled delivery for better patient experience, and optimized therapeutic outcomes.



Additionally, the Company has entered into multiple licensing agreements that provide the Company with additional access to IP from over 20 more patents or patent applications, including the acquisition of an exclusive license to a targeted class of tryptamine-based molecules from Mindset. The licensing agreements collectively provide the Company with access to a broad range of preclinical molecule combinations for its library of psychedelic derivative drug development candidates.

The Company has also filed applications for registration of twenty-four trademarks, including Changing Minds™, Cybin®, Embark™, It's not magic. It's mushrooms™, It's not magic, its science™, Journey™, Mushroom & Friends™, Psilotonin™, Psychedelics to Therapeutics®, MindClef™ and CYB™. The Company has registered the CYBIN trademark in the European Union (the "EU") (reg. 18495520), the UK (reg. UK00003656496), and the US (reg. 6,852,975) and the mark PSYCHEDELICS TO THERAPEUTICS in the UK (reg. UK00003717706).

The Company's mission to discover, develop and deploy psychedelic inspired medicines encompasses the research and development of potential new and improved psychedelic inspired medicines ranging from proprietary psychedelic compounds for use as API, specific formulations thereof, and specific uses for compounds and formulations. As the Company generates new data it will continue to file or acquire additional patent applications throughout the Company's development program.

On July 8, 2021, the Company announced its scaling up of its European operations through its recently formed wholly owned Ireland subsidiary, Cybin Ireland. In connection with the formation of Cybin Ireland, the Company transferred its intellectual property assets to this entity.

### ***Regulatory Framework and Licensing Regime***

#### *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.

Health Canada has not approved psilocybin as a drug for any indication. However, there are legal routes through which psilocybin may be accessed for medical or scientific purposes. The Canadian Minister of Health can grant exemptions under section 56 of the CDSA to use controlled substances if it is deemed to be necessary for a medical or scientific purpose or is otherwise in the public interest. The Company has not applied for a Section 56 Exemption from Health Canada. Health Canada's Special Access Program ("**SAP**") was designed to provide Canadians to access certain restricted drugs before they are formally approved for use in Canada. In January 2022, certain amendments to the SAP came into force to permit medical practitioners treating patients with serious or life-threatening conditions to request access to restricted drugs that have not yet been approved for sale in Canada when conventional therapies have failed, are unsuitable, or unavailable in Canada. Such amendments create a means of legally accessing psilocybin through the SAP. The Company has not applied for access under the SAP.

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).

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 licences and approvals described above.

#### *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 its Deuterated Psilocybin Analog Program upon completion of its preclinical studies and CMC development<sup>26</sup>. Anticipated timelines related to regulatory filings are based on reasonable assumptions informed by current knowledge and information available to the Company.

Psilocybin, psilocin, DMT, and 5-Methoxy-DMT 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 DEA and obtain DEA approval of the research proposal. A majority of state laws in the United States also 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.

#### *Europe (Netherlands)*

The International Narcotics Control Board (“INCB”), a United Nations (“UN”) entity, monitors enforcement of restrictions on controlled substances. The INCB's authority is defined by three international UN treaties – the UN Single Convention on Narcotic Drugs of 1961, the UN Psychotropic Convention of 1971 (referred to herein as the UN71), and the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, which contains provisions related to the control of controlled substance precursors. EU Member States, including the Netherlands, that have agreed to abide by the provisions of these treaties, each create responsible agencies and enact laws or regulations to implement the requirements of these conventions.

Specific EU legislation establishing different classes of controlled substances is limited to EU regulations that define classes of precursors, or substances used in the illicit manufacture of controlled substances, including Regulation (EC) No. 273/2004 of the European Parliament and the Council of February 11, 2004 and the Council Regulation (EC) No. 111/2005 of December 22, 2004. While EU legislation does not establish different classes of narcotic drugs or psychotropic substances, the Council Decision 2005/387/JHA of May 10, 2005 can provoke a Council Decision requiring EU member states to put a drug under national controls equivalent to those of the INCB. DMT is currently

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<sup>26</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”.

classified as a Schedule I substance under the UN71; the EU member states that are party to the UN71, including the Netherlands, have agreed to the following in respect of Schedule I substances:

- prohibit all use except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them;
- require that manufacture, trade, distribution and possession be under a special licence or prior authorization;
- provide for close supervision of the activities and acts mentioned in paragraphs (a) and (b);
- restrict the amount supplied to a duly authorized person to the quantity required for his authorized purpose;
- require that persons performing medical or scientific functions keep records concerning the acquisition of the substances and the details of their use, such records to be preserved for at least two years after the last use recorded therein; and
- prohibit export and import except when both the exporter and importer are the competent authorities or agencies of the exporting and importing country or region, respectively, or other persons or enterprises which are specifically authorized by the competent authorities of their country or region for the purpose.

As classification of controlled substances may vary among different EU member states, sponsors must be aware of the prevailing legislation in each country where a clinical trial may be conducted. Prior to operating or conducting any preclinical or clinical studies in any other EU member state, Cybin will investigate the specific regulatory requirements of such EU member state. As referenced above, a licence is required for individuals and entities who wish to produce, dispense, import, or export Schedule I substances (including DMT), but the specific requirements vary from country to country. Currently, DMT is classified in the Netherlands as a List 1 Drug under the Dutch Opium Act (Opiumwet) (the “**Dutch Opium Act**”) and as such, subject to express authorization being obtained, the production, trade and possession of DMT are prohibited.

In addition to the Dutch Opium Act, two other Dutch Acts may be relevant when it comes to drugs: the Medicines Act and the Commodities Act.

The specific regulatory processes and approvals required may vary among different EU member states and are set forth in the respective legislation of each country. For The Netherlands, there are specific regulatory requirements for the approval of clinical trials that need to be met. Firstly, a CTA (Clinical Trial Application) dossier containing the preclinical and any clinical information along with the proposed clinical trial design must be submitted to an accredited Ethics Committee and to the Central Commission on Research in Humans (the “**CCMO**”), which is also known as the Competent Authority in The Netherlands. In Dutch, the CCMO is called the ‘*Centrale Commissie Mensgebonden Onderzoek*’. In cases where the study involves a substance subject to the Dutch Opium Act (such as DMT), an official exemption by Farmatec is needed, which needs to be included in the CTA.

Specific rules for the submission, assessment and conduct of clinical trials with medicinal products are set out in, among others, the EU Clinical Trial Regulation 536/2014 (CTR), which is applicable in the EU as of January 31, 2022 and the Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen).

### *United Kingdom*

In the UK, there are two main “layers” of regulation with which products containing controlled substances must comply. These are: (i) controlled drugs legislation, which applies to all products irrespective of the type of product, and (ii) the regulatory frameworks applicable to a specific category of products, in this case, pharmaceuticals and food/food supplements.

The main UK controlled drugs legislation is the Misuse of Drugs Act 1971 (the “**MDA**”) and the Misuse of Drugs Regulations 2001 (the “**MDR**”), each as amended. The MDA sets out the penalties for unlawful production, possession and supply of controlled drugs based on three classes of risk (A, B and C). The MDR sets out the permitted uses of controlled drugs based on which Schedule (1 to 5) they fall within.

In the United Kingdom, “Fungus (of any kind) which contains psilocin or an ester of psilocin” is controlled as a Class A drug under the MDA and Schedule 1 drug under the MDR. As psilocybin is a phosphate ester of psilocin, even if it is isolated from psilocin, it will still be treated as a Class A drug under the MDA and as a Schedule 1 drug under the MDR.

In the United Kingdom, Class A drugs are deemed to be the most dangerous, and so carry the harshest punishments for unlawful manufacture, production, possession and supply. Schedule 1 drugs can only be lawfully manufactured, produced, possessed and supplied under a controlled drugs domestic licence issued by the UK Home Office. While exemptions do exist, none are applicable to the API.

The Company previously mentioned that it intended to file a clinical trial application with the U.K. Medicines and Healthcare products Regulatory Agency (the “MHRA”) related to the Deuterated Psilocybin Analog Program upon completion of its pre-clinical studies and CMC development. The Company has since decided that it will first proceed in the U.S. and will reevaluate other applications at a later date. Anticipated timelines related to regulatory filings are based on reasonable assumptions informed by current knowledge and information available to the Company.

### Licensing Requirements

The Company obtains CYB003 API from a pharmaceutical ingredient provider who is FDA-registered and based in the United States. The API itself has been manufactured and packaged in FDA-registered facilities in the United States. The API is expected to be sent directly to the Company’s partners for research and development purposes in the United States, Canada and the UK and to its clinical trial site in the U.S. As a part of the Asset Acquisition, the Company also acquired API. The CYB004-E API was manufactured in the Netherlands by a pharmaceutical ingredient provider that is US FDA-inspected<sup>27</sup>.

Although the facilities in the UK are currently FDA-registered, this would not be sufficient to ensure the existence of valid marketing activities at this site. As mentioned above, in order to produce, possess and supply the API, the UK-based facility must also hold a domestic licence issued by the Home Office covering the manufacture, production, possession and supply of a controlled substance, as well as an export licence for each API shipment. The export application must include details of the importer and any import licence required by the local authorities in the United States. Moreover, as set out below in more detail under the heading “Pharmaceutical Products”, depending on how the API is developed, certain authorizations and licences from the MHRA may be required to authorize some of the activities carried on at the UK-based facilities in relation to the API.

All premises that are licensed, or are intending to be licensed, in connection with the possession, and/or supply and/or production of controlled drugs should consider certain security measures.<sup>28</sup>

Typically, when controlled drugs are being transported between licensees, responsibility for their security remains with the owner and does not transfer to either the courier or the customer until the drugs arrive at their destination and are signed for. However, where a third party is involved in the transit and/or storage of controlled drugs, even if they are not the legal owners, this party also carries responsibility for their security by virtue of being ‘in possession’ of them. Under the Home Office guidance, each organization involved in the movement of controlled drugs should have a standard operating procedure covering their responsibilities, record keeping, reconciliation and reporting of thefts/losses.<sup>29</sup>

### Pharmaceutical Products

A product is regulated as a “medicinal product” under UK legislation (the Human Medicines Regulations 2012) if (i) it is a substance or combination of substances presented as having properties of preventing or treating disease in human beings (e.g., in marketing claims) or (ii) it is a substance or combination of substances that may be used by or administered to human beings with a view to (a) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or (b) making a medical diagnosis.

Whether a specific product restores, corrects or modifies a physiological function by exerting a pharmacological, immunological or metabolic action will depend on factors such as the concentration of the psilocybin/psilocin and the mode of action of any psilocybin/psilocin absorbed in the body.

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<sup>27</sup> As a result of the Asset Acquisition, including the existing API, the Company did not direct the manufacturing of the API for CYB004-E and proceeded in reliance upon the representations of Entheon and the Company’s acquisition diligence. While the Company believes the CYB004-E API meets all required specifications, the Company did not oversee or direct the manufacture of the DMT API being used in CYB004-E.

<sup>28</sup> Home Office guidance; Security guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants; 2022; [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1125889/Security\\_Guidance\\_for\\_all\\_Businesses\\_and\\_Other\\_Organisations\\_v1.5\\_Nov\\_2022.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1125889/Security_Guidance_for_all_Businesses_and_Other_Organisations_v1.5_Nov_2022.pdf)

<sup>29</sup> Home Office guidance; Guidelines for Standard Operating Procedures (SOPs); [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/480572/StandardOpProcedure.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/480572/StandardOpProcedure.pdf)

If a product is a medicinal product, a marketing authorization for the product is required before the product can be placed on the market in the UK. The process for obtaining a marketing authorization involves submitting preclinical and clinical data as well as quality and manufacturing information in the form of a common technical document. In addition to a marketing authorization for the product itself, companies carrying out activities involving medicinal products, such as manufacturing, distribution and wholesaling, need to meet defined standards (Good Manufacturing Practices (“**GMP**”)) and/or Good Distribution Practice (“**GDP**”) and to hold a related licence from the MHRA.

How the API is subsequently processed will determine the licences that the UK-based facility must hold. In particular:

- if the API is just one ‘ingredient’ of the investigational medicinal product (the “**IMP**”) which is used in the clinical trial then the UK-based facility must register with the MHRA and provide the MHRA with 60 days’ notice of the intended start of manufacture/distribution of the API, and comply with GMP and GDP for active substances; and
- conversely, if the API will itself constitute the IMP, the manufacturer must, except in certain limited circumstances, hold a Manufacturer’s Authorizations for IMPs licence (“**MIA(IMP)**”). In this scenario, an MIA(IMP) would be required regardless of whether the IMP is for use in the UK, an EEA Member State or a third country (such as the United States or Canada).

Some products fall on the borderline between medicines and another category such as medical devices, cosmetics or food supplements. The regulatory status of the product will be determined by i) the actual effect of the product on the body; and ii) any claims made about the effect of the product. Where a product is potentially both a medicinal product and another category of product, the legal position in the UK and EU is that it will be regulated as a medicinal product.

## Research and Development

The Company is focused on development of psychedelic medicines and other products, through research and development of novel chemical compounds and delivery mechanisms and study of such compounds in clinical environments around the world. The Company anticipates growing its pipeline of psychedelic pharmaceutical products inspired medicines through its internal research, development, proprietary discovery programs, mergers and acquisitions, joint ventures and collaborative development agreements. For the time being, the Company maintains intellectual property generated by its R&D programs through patent filings and as trade secrets. The Company anticipates that as these programs mature more patent applications will be filed and more details about these programs will be disclosed at such time.

As a result of COVID-19, certain institutions have implemented certain facility procedures and are utilizing technology in an effort to mitigate the effects of the pandemic, specifically by moving patient interactions to remote status wherever possible. The Company cannot guarantee that the continued effects of COVID-19 will not impact patient recruiting for clinical trials and institutional processes at institutions involved in pharmaceutical product development.

Psychedelics are a class of drug whose primary action is to trigger psychedelic experiences by way of serotonin receptor agonism, causing thought, visual and auditory changes, and altered state of consciousness. Major psychedelic drugs include mescaline, LSD, psilocybin, and DMT. Psilocybin is a naturally occurring psychedelic prodrug compound produced by more than 200 species of mushrooms, collectively known as psilocybin mushrooms. The most potent are members of the genus *Psilocybe*, such as *P. azurescens*, *P. semilanceata*, and *P. cyanescens*, but psilocybin has also been isolated from about a dozen other genera. As a prodrug, psilocybin is quickly converted by the body to psilocin, which has mind-altering effects.

The pharmacokinetics, pharmacology and human metabolism of psilocybin are well known and well characterized. In conjunction with psychotherapy, psilocybin has been utilized broadly in phase II clinical trials.

Psilocybin found in certain species of mushrooms is a non-habit forming naturally occurring psychedelic compound. Once ingested, psilocybin is rapidly metabolized to psilocin, which then acts on serotonin receptors in the brain.

Cybin has commenced research and development on the delivery of synthetic psilocybin and other psychedelics through mechanisms such as sublingual film delivery, ODT, IV, and by way of inhalation.

Research and development is led by the Company's North American Chief Scientific Officer, Alex Nivorozhkin Ph.D., a seasoned medicinal chemist, drug delivery expert and founder of multiple biotech companies.

The Company's research and development must be conducted in strict compliance with the regulations of federal, state, local and regulatory agencies in Canada, the United States, and the UK, and the equivalent regulatory agencies in the other jurisdictions in which the Company operates. These regulatory authorities regulate, among other things, the research, manufacture, promotion and distribution of drugs in specific jurisdictions under applicable laws and regulations.

#### Canada

The process required before a prescription drug product candidate may be marketed in Canada generally involves:

- *Chemical and Biological Research* – Laboratory tests are carried out on tissue cultures and with a variety of small animals to determine the effects of the drug. If the results are promising, the manufacturer will proceed to the next step of development.
- *Preclinical Development* – Animals are given the drug in varying amounts over differing periods of time. If it can be shown that the drug causes no serious or unexpected harm at the doses required to have an effect, the manufacturer will proceed to clinical trials.
- *Clinical Trials – Phase 1* - The first administration in humans is to test if people can tolerate the drug. If this testing is to take place in Canada, the manufacturer must prepare a clinical trial application for the Therapeutic Products Directorate of Health Canada (the “TPD”). This includes the results of the first two steps and a proposal for testing in humans. If the information is sufficient, the Health Products and Food Branch of Health Canada (the “HPFB”) grants permission to start testing the drug, generally first on healthy volunteers.
- *Clinical Trials – Phase 2* - Phase 2 trials are carried out on people with the target condition, who are usually otherwise healthy, with no other medical condition. Trials carried out in Canada must be approved by the TPD. In phase II, the objective of the trials is to continue to gather information on the safety of the drug and begin to determine its effectiveness.
- *Clinical Trials – Phase 3* - If the results from phase II show promise, the manufacturer provides an updated clinical trial application to the TPD for phase III trials. The objectives of phase III include determining whether the drug can be shown to be effective, and have an acceptable side effect profile, in people who better represent the general population. Further information will also be obtained on how the drug should be used, the optimal dosage regimen and the possible side effects.
- *New Drug Submission* – If the results from phase III continue to be favourable, the drug manufacturer can submit a new drug submission (“NDS”) to the TPD. A drug manufacturer can submit an NDS regardless of whether the clinical trials were carried out in Canada. The TPD reviews all the information gathered during the development of the drug and assesses the risks and benefits of the drug. If it is judged that, for a specific patient population and specific conditions of use, the benefits of the drug outweigh the known risks, the HPFB will approve the drug by issuing a notice of compliance.

#### United States

Because psilocybin, psilocin, DMT, and 5-Methoxy-DMT are listed as Schedule I substances under the CSA, 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.

The process required before a prescription drug product candidate may be marketed in the United States generally involves:

- completion of extensive non-clinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory, Good Clinical and/or Good Manufacturing Practice regulations;
- submission to the FDA of an IND, which the FDA must approve before human clinical trials may begin;

- approval by an IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the prescription drug product candidate for each proposed indication;
- submission to the FDA of a New Drug Application ("**NDA**");
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, and purity; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and the Company cannot be certain that the DEA will schedule or reschedule any Schedule I substance or product candidate to Schedule II, III, IV, or V, or that approvals for its prescription drug product candidates will be granted on a timely basis, if at all.

Non-clinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of non-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some non-clinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements.

An IRB board, at each of the clinical centers proposing to conduct the clinical trial, must review and approve the plan for any clinical trial before it commences at that center. An IRB board considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB board also approves the consent form signed by the trial participants and must monitor the study until completed. The FDA, the independent IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries.

The FDA offers a number of regulatory mechanisms that provide expedited or accelerated approval procedures for selected drugs and indications which are designed to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These include programs such as Breakthrough Therapy designations, Fast Track designations, Priority Review and Accelerated Approval, which the Company may need to rely upon in order to receive timely approval or to be competitive.

The Company may plan to seek orphan drug designation for certain indications qualified for such designation. The U.S., E.U. and other jurisdictions may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which, in the U.S., is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. In the E.U., orphan drug designation can be granted if: the disease is life threatening or chronically debilitating and affects no more than 50 in 100,000 persons in the E.U.; without incentive it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. Orphan drug designation must be requested before submitting an NDA. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. and 10 years in the E.U. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the development, review and approval process. However, this designation provides an exemption from marketing and authorization fees.

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, and complying with promotion and advertising requirements. The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including current Good Manufacturing Practices, which impose certain procedural and documentation requirements. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a risk evaluation and mitigation strategy.

In the United States, pharmaceutical manufacturers are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the Anti-Kickback Statute, the federal *False Claims Act* (the "FCA"), and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid.

The FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to or approval by the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Violations of the FCA can result in very significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, the federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. In addition, a similar federal requirement Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Affordable Care Act, commonly referred to as the "Physician Payments Sunshine Act" requires applicable manufacturers to track and report to the federal government certain payments and "transfers of value" made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, made in the previous calendar year. There are a number of states that have various types of additional reporting requirements.



## *Controlled Substances*

The CSA and its implementing regulations establish a “closed system” of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. For any product containing a Schedule I substance, such as psilocybin, 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.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration and periodically to ensure continued compliance. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA’s estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

Individual U.S. states also establish and maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. A majority of state laws in the United States classify psilocybin and psilocin as Schedule I controlled substances. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on the Company’s business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

## Netherlands

Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use ( the “**CTR**”) is applicable as of January 31, 2022, harmonizing the laws, regulations and administrative provisions of the EU Member States relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. EU Member States have transformed the requirements outlined in the Clinical Trials Directive into the respective national laws. Pursuant to the CTR, as of January 31, 2023 sponsors are obliged to use the Clinical Trials Information System (CTIS) for regularity submission, authorization and supervision of clinical trials in the EU and the EEA. CTIS will thus serve as the single-entry point for submissions by sponsors and for regulatory assessment. In addition to this obligation, sponsors must transfer any ongoing (approved) trials under the CTR to CTIS by January 2025.

The IMPD is one of several regulatory documents required for conducting a clinical trial of a pharmacologically API intended for one or more EU Member States. The IMPD includes summaries of information related to the quality, manufacture and control of any Investigational Medicinal Product (including reference product and placebo) (“**IMP**”), and data from non-clinical and clinical studies. Guidance concerning IMPDs is based on the CTR and on the approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (also commonly referred to as the “Clinical Trials Directive”).

The content of the IMPD may be adapted to the existing level of knowledge and the product’s phase of development. When applying for a clinical trial authorization, a full IMPD is required when little or no information about an API has been previously submitted to competent authorities, when it is not possible to cross-refer to data submitted by another sponsor and/or when there is no authorization for sale in the EU. However, a simplified IMPD may be submitted if information has been assessed previously as part of a Marketing Authorization or a clinical trial to that competent authority. Although the format is not obligatory, the components of an IMPD are largely equivalent to clinical trial applications in Canada and the United States. The IMPD need not be a large document as the amount of information to be contained in the dossier is dependent on various factors such as product type, indication, development phase etc.

The assessment of an IMPD is focused on patient safety and any risks associated with the IMP. Whenever any potential new risks are identified the IMPD must be amended to reflect the changes. Certain amendments are considered substantial in which case the competent authority must be informed of the substantial amendment. This may be the case for changes in IMP impurities, microbial contamination, viral safety, transmissible spongiform encephalopathies (e.g. mad cow disease) and in some particular cases to stability when toxic degradation products may be generated.

With the completion of the Asset Acquisition, the Company has an ongoing phase I study to obtain preliminary evidence of the safety and efficacy of infused DMT. Prior to the Asset Acquisition, an investigator’s brochure (including prior safety, preclinical and clinical data), and an IMPD document that includes CMC information and a clinical study protocol and supporting information had been prepared. Approval by the Dutch ethics committee of the Phase 1 Study, planned to be conducted by CHDR will be based on the vast amount of published human and animal studies of DMT. Prior to the Asset Acquisition, preclinical data was not provided as part of the application package; however, limited additional in vivo and in vitro data to support the rationale for human dosing and safety had been included. CHDR and its partner GMP-licensed pharmacy that will be involved in the Phase 1 Study, the Leiden University Medical Center, have all the required approvals to possess and handle DMT for the Phase 1 Study.

Failure of the Company to receive the necessary regulatory approvals required to conduct the Phase 1 Study would have an adverse impact on its business plans and financial condition for a number of reasons including, without limitation: (i) it would cause delays in the Company’s research and development plans; (ii) it may require the Company to expend additional financial and human resources on revising its application package or creating a new one; or (iii) it may require the Company to approach an entirely different regulatory authority in a new jurisdiction, in which case the Company would have to expend a substantial amount of capital and other resources on engaging the appropriate research and development partners and creating an application package that complies with the regulations of that new jurisdiction. Additionally, the Company would be required to spend capital on transferring the DMT materials to the new jurisdiction. All of the foregoing would likely have a negative impact on the Company’s business and financial condition.

In accordance with the Dutch Medicines Act (*Geneesmiddelenwet*), “medicinal products” are defined as: a substance or a combination of substances that is intended to be administered or used for, or is presented in any way as being suitable for, use: (i) the cure or prevention of any disease, defect, wound or pain in human beings, (ii) the making of a medical diagnosis in human beings, or (iii) restoring, improving or otherwise modifying physiological functions in humans by exerting a pharmacological, immunological or metabolic effect.

If a product constitutes a medicinal product, a marketing authorization for the product is required before the product may be placed on the market in the Netherlands. In the EU, marketing authorizations may be obtained through the Centralized procedure, the Decentralized procedure and/or the national procedure. The Centralized procedure is compulsory for medicines intended to treat i.e. cancer, AIDS, neurodegenerative diseases and diabetes and optional (only) for medicines comprising of new active substances not previously approved for the EEA. When applying for a marketing authorization through the Centralized procedure, applications are submitted with the European Medicines Agency (the “EMA”). Where the Centralized procedure is not available but a medicinal product is intended for several EU/EEA Member States, an application for a marketing authorization may be submitted with the competent authority of a single EU/EEA Member State in accordance with the Decentralized procedure. When the assessment of the application results in a decision to grant the marketing authorization, this decision will be mutually recognized by the competent authorities of the other Member States for which the marketing authorization is applied. Finally, should a medicinal product be intended for the Netherlands only, then the national procedure may be followed as well by submitting an application with the Dutch Medicines Evaluation Board. It may be remarked that the national procedure is unavailable in case the Centralized procedure is compulsory or in case an applicant has already submitted an application for and/or obtained a marketing authorization in another Member State. In that case, applications must follow the mutual recognition procedure instead.

Companies that manufacture or trade in medicinal products and/or active pharmaceutical ingredients in the Netherlands require a manufacturing authorization or a wholesale distribution authorization. A manufacturing authorization is required for the preparation, trading in, import and export of medicinal products and/or active substances. Here, ‘preparation’ means the total or partial manufacture of medicinal products and/or active substances or the packaging or labelling thereof. ‘Importing’ means the import of medicinal products or active substances from a country outside the EEA into the Dutch territory, while ‘exporting’ means the export of medicinal products or active substances from the Dutch territory to a country outside the EEA. A wholesale distribution authorization is required for one or more activities within the wholesale business, such as procuring, holding, supplying, delivering or exporting medicinal products or active substances which are prepared or imported by a third party. It may be noted that holders of wholesale distribution authorization, other than holders of marketing authorizations, are not authorized to import medicinal products from countries outside the EEA.

Only a natural or legal person established in the Netherlands may obtain either a Dutch marketing authorization or a wholesale distribution authorization. These authorizations concern national permits, meaning that these authorizations are not automatically valid in other EU Member States. Furthermore, in the Netherlands applicants of marketing authorizations and wholesale distributions authorizations must be registered with Farmatec and comply with GDP norms.

### *Market Authorization Regulatory Process*

Under the Centralized procedure, pharmaceutical companies submit a single marketing authorization application to the EMA, which provides the basis of a legally binding recommendation that will be provided by the EMA to the European Commission, the authorizing body for all centrally authorized products. This allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorization. EMA’s Committee for Medicinal products for Human Use or Committee for Medicinal Products for Veterinary Use carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not, under any particular dosing regime. Although, under EU law, the EMA has no authority to permit marketing in the different EU countries, the European Commission is the authorizing body for all centrally authorized products, who takes a legally binding decision based on EMA’s recommendation. Once granted by the European Commission, the centralized marketing authorization is valid in all EU Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. European Commission decisions are published in the Community Register of medicinal products for human use. Once a medicine has been authorized for use in the EU, the EMA and the EU Member States constantly monitor its safety and

take action if new information indicates that the medicine is no longer as safe and effective as previously thought. The safety monitoring of medicines involves a number of routine activities ranging from: assessing the way risks associated with a medicine will be managed and monitored once it is authorized; continuously monitoring suspected side effects reported by patients and healthcare professionals, identified in new clinical studies or reported in scientific publications; regularly assessing reports submitted by the Company holding the marketing authorization on the benefit-risk balance of a medicine in real life; and assessing the design and results of post-authorization safety studies which were required at the time of authorization. The EMA can also carry out a review of a medicine or a class of medicines upon request of a Member State or the European Commission. These are called EU referral procedures; they are usually triggered by concerns in relation to a medicine's safety, the effectiveness of risk minimization measures or the benefit-risk balance of the medicine. The EMA has a dedicated committee responsible for assessing and monitoring the safety of medicines, the Pharmacovigilance Risk Assessment Committee. This ensures that EMA and the EU Member States can move very quickly once an issue is detected and take any necessary action, such as amending the information available to patients and healthcare professionals, restricting use or suspending a medicine, in a timely manner in order to protect patients.

Besides the Centralized procedure, pharmaceutical companies may also submit marketing authorization applications through the Decentralized procedure with the competent authority of a Member State. As the Centralized procedure is compulsory for medicines intended to treat specified diseases i.e. cancer, AIDS, neurodegenerative diseases and diabetes and only optional for medicines comprising of new active substances not previously approved for the EU/EEA, in all other circumstances the Decentralized procedure should be used instead if a marketing authorization is to be obtained for several EU/EEA Member States. When following the Decentralized procedure, the applicant requests one country to be the Reference Member State ("RMS") in the procedure. After having shared draft assessment reports to which both the applicant and the competent authorities of other Member States may respond, the to be granted marketing authorization will eventually go through the Mutual recognition procedure. In the Mutual recognition procedure other Member States generally adopt the RMS's assessment, unless there are important objections on the grounds of a potentially serious risk to public health. In such situations, further discussions will also be held in the Co-ordination group for Mutual recognition and Decentralised procedures ("CMDh"). When all Member States involved decide on a positive opinion on products in the CMDh, Dutch translations of the summary of product characteristics, package leaflet, labelling texts and mock-ups are submitted and a national marketing authorization is issued.

## Ireland

In Ireland, psilocin is a controlled substance under the *Misuse of Drugs Act, 1977, 1984 and 2015* (the "**Ireland MDA**"), the *Misuse of Drugs Regulations 2017* (the "**Ireland MDR**") and the *Criminal Justice (Psychoactive Substances) Act 2010*. These are the primary legislative instruments which govern controlled substances in Ireland. This legislation regulates the use, possession, supply, licensing, and administration of listed scheduled substances and establishes the offences and penalties for anything done contrary to the legislation.

Any substance, product or preparation (whether natural or otherwise) including a fungus of any kind or description, which contains psilocin or an ester of psilocin is controlled as a Schedule 1 controlled substance under the Ireland MDA and the Ireland MDR. The Ireland MDR includes "any substance, product or preparation including fungi of any kind or description, containing psilocin or an ester of psilocin (which are commonly described as 'magic mushrooms')" within the strict regime of control that applies to those substances in Schedule 1 of the Ireland MDR. Accordingly, psilocin will qualify as a Schedule 1 controlled substance and is subject to the strict regime of control that applies.

As a Schedule 1 controlled substance under the Ireland MDA, unlawful manufacturing, production, preparation, importation, exportation, supply, or distribution of psilocin carries onerous obligations and harsh punishments for contravention; this include fines and/or terms of imprisonment of up to 14 years.

Pursuant to the Ireland MDA, in certain circumstances, the Minister for Health "may grant licences or issue permits or authorizations for any of the purposes of this Act, attach conditions to any such licence, permit or authorization, vary such conditions and revoke any such licence, permit or authorization". Where licences are granted, there are very strict conditions imposed on licence holders. For example, strict conditions can be placed regarding the security, storage and documenting controlled substances.

The Company does not currently engage in any activities in Ireland that are regulated by such laws. If the Company were to engage in such activities, it would need to obtain the appropriate licences and authorization to do so. The Company intends to constantly review its Irish operations to ensure compliance with all applicable laws as the operations evolve.

### **Compliance with Applicable Laws**

The Company oversees and monitors compliance with applicable laws in each jurisdiction in which it operates. In addition to the Company's senior executives and the employees responsible for overseeing compliance, the Company has local counsel engaged in every jurisdiction in which it operates and has received legal opinions or advice in each of these jurisdictions regarding (a) compliance with applicable regulatory frameworks, and (b) potential exposure to, and implications arising from, applicable laws in jurisdictions in which the Company has operations or intends to operate.

The Company works with third parties who require regulatory licensing to handle scheduled drugs. The Company continuously updates its compliance and channel programs to maintain regulatory standards set for drug development. The Company also works with clinical research organizations who maintain batch records and data storage for the Company's clinical programs.

Additionally, the Company has established a Medical & Clinical Advisory Team, a Research, Clinical and Regulatory Team and a Government Relations and Communications Team with cross-functional expertise in business, neuroscience, pharmaceuticals, mental health and psychedelics to advise management.

In conjunction with the Company's human resources and operations departments, the Company oversees and implements training on the Company's protocols. The Company will continue to work closely with external counsel and other compliance experts, and is evaluating the engagement of one or more independent third party providers to further develop, enhance and improve its compliance and risk management and mitigation processes and procedures in furtherance of continued compliance with the laws of the jurisdictions in which the Company operates.

The programs currently in place include monitoring by executives of the Company to ensure that operations conform to and comply with required laws, regulations and operating procedures. The Company is currently in compliance with the laws and regulations in all jurisdictions and the related licensing framework applicable to its business activities.

The Company and, to its knowledge, each of its third-party researchers, suppliers and manufacturers have not received any non-compliance, citations or notices of violation which may have an impact on the Company's licences, business activities or operations.

The Company conducts due diligence on third-party researchers, medical professionals, clinics, cultivators, processors and others as applicable, with whom it engages. Such due diligence includes but is not limited to the review of necessary licenses and the regulatory framework enacted in the jurisdiction of operation. Further, the Company generally obtains, under its contractual arrangements, representations and warranties from such third parties pertaining to compliance with applicable licensing requirements and the regulatory framework enacted in the jurisdiction of operation.

### **Patent Cooperation Treaty**

The PCT facilitates filing for patent recognition in multiple jurisdictions simultaneously using a single uniform patent application. 157 countries, including Canada and the United States have ratified the PCT.

Ultimately, patents are still granted in each country individually. As such, the PCT procedure consists of two phases: filing of an international application, and national evaluation under the patent laws in force in each country where a patent is sought.

Within 12 months of filing a provisional patent application at the United States Patent and Trademark Office, the Company may elect to file a regular utility patent application in the United States in tandem with filing a PCT application with the World Intellectual Property Office, in each case claiming priority to the provisional patent application. Within 30 months of the provisional filing date, deadlines begin for a PCT application to enter the

national phase in desired jurisdictions globally, such as Canada (30 months) and Europe (31 months), in each case claiming priority to the provisional patent application.

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. The Company is exploring drug development within approved laboratory clinical trial settings conducted within approved regulatory frameworks. Though highly speculative, should any prescription drug product be developed by the Company (which, if it does occur, would not be for several years), such drug product will not be commercialized prior to receipt of applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended use(s) is successfully developed. The Company may also employ non-prescription drugs, where appropriate.

### ***Selected Quarterly Information***

The following table sets forth selected consolidated financial information for the periods indicated that are derived from, and should be read in conjunction with, the Financial Statements and related notes thereto.

<i>(Canadian dollars in thousands, except per share and share figures)</i>	<b>March 31, 2023</b>	<b>December 31, 2022</b>	<b>September 30, 2022</b>	<b>June 30, 2022</b>	<b>March 31, 2022</b>	<b>December 31, 2021</b>	<b>September 30, 2021</b>	<b>June 30, 2021</b>
<b>Revenues (\$)</b>	—	—	—	—	—	—	—	—
<b>Operating Expenses (\$)</b>	13,703	12,093	12,327	13,395	16,338	16,455	17,106	13,939
<b>Net loss (\$)</b>	(13,720)	(10,742)	(9,973)	(13,055)	(18,097)	(17,210)	(17,607)	(14,717)
<b>Weighted Average Shares - Basic</b>	196,144,381	188,887,344	180,837,176	175,874,475	173,873,017	171,833,544	165,783,294	157,711,518
<b>Loss per share (\$'s)</b>	(0.07)	(0.06)	(0.06)	(0.07)	(0.10)	(0.10)	(0.11)	(0.09)
<b>Weighted Average Shares - Diluted</b>	196,144,381	188,887,344	180,837,176	175,874,475	173,873,017	171,833,544	165,783,294	157,711,518
<b>Loss per share (\$'s)</b>	(0.07)	(0.06)	(0.06)	(0.07)	(0.10)	(0.10)	(0.11)	(0.09)
<b>Cash and cash equivalents</b>	16,633	22,511	29,937	42,460	53,641	63,580	75,179	55,075
<b>Total Assets (\$)</b>	53,897	60,694	69,113	74,590	84,063	95,161	105,465	82,837
<b>Total Non-Current Liabilities (\$)</b>	—	—	—	—	—	—	363	770

## ***Selected Annual Information***

The following table presenting the Company's results of operations as at and for the three most recently completed financial years ending March 31 should be read in conjunction with the Financial Statements and related notes thereto.

The Company's selected financial information as at and for the three most recently completed financial years ended March 31, are summarized as follows:

<i>(Canadian dollars in thousands, except per share and share figures)</i>	<b>For the year ended March 31, 2023</b>	<b>For the year ended March 31, 2022</b>	<b>For the year ended March 31, 2021</b>
<b>Revenues (\$)</b>	—	—	864
<b>Operating Expenses (\$)</b>	<b>51,518</b>	63,838	30,724
<b>Net loss (\$)</b>	<b>(47,490)</b>	(67,631)	(32,220)
<b>Weighted Average Shares - Basic</b>	<b>185,428,767</b>	167,287,240	100,010,864
<b>Loss per share (\$'s)</b>	<b>(0.26)</b>	(0.40)	(0.32)
<b>Weighted Average Shares - Diluted</b>	<b>185,428,767</b>	167,287,240	100,010,864
<b>Loss per share (\$'s)</b>	<b>(0.26)</b>	(0.40)	(0.32)
<b>Cash and cash equivalents</b>	<b>16,633</b>	53,641	64,026
<b>Total Assets (\$)</b>	<b>53,897</b>	84,063	92,112
<b>Total Non-Current Liabilities (\$)</b>	—	—	1,094

The Company has not paid dividends on the Common Shares and does not anticipate declaring any dividends in the near future.

## **Assets**

Total assets decreased by \$30,166 from March 31, 2022 to March 31, 2023 mainly as a result in a decrease in cash as the Company continues to progress its operations. The decrease is partially offset by an increase in accounts receivable, prepaid expenses, other current assets, and the impact of foreign exchange on translation. As at March 31, 2023, the Company had prepaid expenses related to future clinical work of \$849 (US\$627).

## **Non-Current Liabilities**

The Company does not currently have any non-current liabilities.

## Results of operations

	Three months ended March 31,		Year ended March 31,	
	2023	2022	2023	2022
<b>EXPENSES</b>				
Research	8,046	5,829	25,491	17,586
General and administrative costs	5,176	7,166	21,341	28,222
Share-based compensation	481	3,343	4,686	18,030
<b>TOTAL EXPENSES</b>	<b>13,703</b>	<b>16,338</b>	<b>51,518</b>	<b>63,838</b>
<b>OTHER INCOME (EXPENSES)</b>				
Foreign currency translation gain (loss)	(40)	(351)	4,027	(309)
Interest income	148	83	603	241
Change in fair value of investments measured at fair value through profit or loss	(125)	(29)	(260)	(29)
Contingent consideration accretion	—	(26)	(13)	(316)
Change in fair value of contingent consideration	—	(1,436)	(329)	(3,380)
<b>TOTAL OTHER INCOME (EXPENSES)</b>	<b>(17)</b>	<b>(1,759)</b>	<b>4,028</b>	<b>(3,793)</b>
<b>NET LOSS FOR THE YEAR</b>	<b>(13,720)</b>	<b>(18,097)</b>	<b>(47,490)</b>	<b>(67,631)</b>
<b>Basic loss per share for the period attributable to common shareholders</b>	<b>(0.07)</b>	<b>(0.10)</b>	<b>(0.26)</b>	<b>(0.40)</b>
<b>Weighted average number of common shares outstanding - basic</b>	<b>196,144,381</b>	<b>173,873,017</b>	<b>185,428,767</b>	<b>167,287,240</b>

For the three and twelve month periods ended March 31, 2023, Cybin incurred a net loss of \$13,720 and \$47,490, respectively, compared to a net loss of \$18,097 and \$67,631 during the same periods in prior year.

During the three and twelve month periods ended March 31, 2023, the Company was focused on progressing its various research programs and raising awareness of the Company and its industry.

During the year ended March 31, 2023, the Company submitted an IND and received a “may proceed letter” and IND clearance from the FDA for its Phase 1/2a first-in-human clinical trial evaluating CYB003 as well as dosed its first patients in the trial. In February 2023, Cybin announced interim data from its ongoing Phase 1/2a clinical trial, which demonstrated rapid and short-acting effects; robust psychedelic effects at low doses; positive safety and tolerability profile. In addition, the Company announced the Asset Acquisition from Entheon to accelerate the clinical development path for CYB004. The initial findings from the Phase 1 CYB004-E study suggest IV DMT was well-tolerated. The Company also completed a protocol amendment to the study design to accelerate first-in-human dosing of CYB004. Furthermore, during the year the Company further strengthened its intellectual property portfolio by entering into multiple licensing agreements that provide Cybin with additional access to IP from over 15 more patents or patent applications (see “Relationships with Third Parties”).

In addition, the Company established an at-the-market equity program (the “ATM Program”) that allows the Company to issue and sell up to US\$35,000 of Common Shares in the capital of the Company from treasury to the public, from time to time. Distributions of Common Shares under the ATM Program, will be made pursuant to the terms and conditions of an “at-the-market equity” distribution agreement (the “Distribution Agreement”) dated August 8, 2022, entered into by and among the Company, Cantor Fitzgerald Canada Corporation and Cantor Fitzgerald & Co. The ATM Program will be effective until the earlier of the issuance and sale of all of the Common Shares issuable pursuant to the ATM Program and August 5, 2023 unless earlier terminated in accordance with the terms of the Distribution Agreement. Up to March 31, 2023, the Company had sold 20,754,120 Common Shares under the ATM program at an average price of US\$0.5079 per Common Share, for aggregate gross proceeds of US\$10,541. During the three month period ended March 31, 2023, the Company had sold 9,495,437 Common Shares under the ATM program at an average price of US\$0.4156 per Common Share, for aggregate gross proceeds of US\$3,947.



## ***Operating expenses***

For the three-month period ended March 31, 2023, operating expenses totaled \$13,703. The operating expenses include a non-cash component of \$481 (2022 - \$3,343) related to share-based compensation. The remaining operating expenses were incurred to support raising capital, research & development and the overall development of the Company.

For the year ended March 31, 2023, operating expenses totaled \$51,518. The operating expenses include a non-cash component of \$4,686 (2022 - \$18,030) related to share-based compensation. The remaining operating expenses were incurred to support raising capital, research & development and the overall development of the Company.

## **Research**

For the three-month period ended March 31, 2023, the Company's research expenses totaled \$8,046 compared to \$5,829 during the same period in prior year. Research expenses for the three-month period ended are comprised of advancement of the development programs of \$4,970 (2022 - \$2,839), payroll related expenses of \$2,551 (2022 - \$2,825), professional and consulting fees of \$310 (2022 - \$117), and lab and administration expenses of \$215 (2022 - \$48).

For the year ended March 31, 2023, the Company's research expenses totaled \$25,491 compared to \$17,586 during the same period in prior year. Research expenses for the year ended March 31, 2023, are comprised of advancement of the development programs of \$14,360 (2022 - \$8,744), payroll related expenses of \$8,830 (2022 - \$6,989), professional and consulting fees of \$1,159 (2022 - \$1,555), lab and administration expenses of \$1,142 (2022 - \$298).

The overall increase in research expenses, for both the three and twelve month periods, are due to growth of the Company and the progression of the Company's various research programs, including two programs in clinical trials. As of the date of this MD&A, Cybin's research and development team has completed over 250 preclinical studies supporting research and development advancement of proprietary psychedelic-based molecules being designed for potential therapeutic applications for several mental health conditions. To date, more than 50 novel compounds have been evaluated through collaborations with experienced contract research organizations for pharmacokinetic/pharmacodynamic profile, metabolic stability, receptor binding, and safety in order to identify preferred candidates for further development. In addition, the Company currently has two clinical-stage programs ongoing.

## **General and administration costs**

For the three-month period ended March 31, 2023, general and administrative expenses were \$5,176 compared to \$7,166 during the same period in prior year. General and administrative expense for the three-month period are comprised of capital market expenses of \$2,271 (2022 - \$1,915), payroll related expenses of \$1,608 (2022 - \$2,620), office and administration expenses of \$685 (2022 - \$791), investor relations expenses of \$271 (2022 - \$373), professional and consulting fees of \$234 (2022 - \$802), listing fees of \$50 (2022 - \$176), business development expenses of \$45 (2022 - \$177), and marketing media fees of \$12 (2022 - \$312). The overall decrease in general and administrative expenses is mainly related to a reduction in the payroll, consulting and benefits spend and professional and consulting fees as a result certain cost cutting measures taken.

For the year ended March 31, 2023, general and administrative expenses were \$21,341 compared to \$28,222 during the same period in prior year. General and administrative expense for year ended March 31, 2023, are comprised of payroll related expenses of \$6,272 (2022 - \$7,468), capital market expenses of \$6,323 (2022 - \$7,277), office and administration expenses of \$3,731 (2022 - \$3,999), professional and consulting fees of \$2,142 (2022 - \$3,275), investor relations expenses of \$984 (2022 - \$1,981), marketing media fees of \$881 (2022 - \$1,466), business development expenses of \$654 (2022 - \$2,223), and listing fees of \$354 (2022 - \$533). The overall decrease in general and administrative expenses relates to a reduction in the payroll, consulting and benefits spend and professional and consulting fees as a result certain cost cutting measures taken. Furthermore, the Company incurred less marketing related spending to raise awareness of the Company and its industry during 2023. The Company continues to incur expenditures related to market awareness, some of which it considers one-time events, but to a lesser extent. The Company expects these expenses to decrease in the next fiscal year.

## **Share-based compensation**

During the three-month period ended March 31, 2023, Cybin issued warrants and options incurring share-based payment expense of \$481 compared to \$3,343 during the same period in prior year. The decrease is largely related to the timing of warrant and option grants.

During the year ended March 31, 2023, Cybin issued warrants and options incurring share-based payment expense of \$4,686 compared to \$18,030 during the same period in prior year. The decrease is largely related to the timing of warrant and option grants.

The share-based compensation expense was recorded based on the fair value using a Black Scholes Model. On exercise of these warrants and options the equity reserve balances will move to share capital.

## ***Other income (expenses)***

### **Foreign exchange gain (loss)**

For the three-month period ended March 31, 2023, the Company incurred a foreign currency translation loss from operations and revaluation of balance sheet assets and liabilities held in foreign currencies of \$40. For the twelve-month period ended March 31, 2023, the Company incurred a foreign currency translation gain of \$4,027, respectively. The Company holds assets and liabilities in Canadian dollars, U.S. dollars, Euros, and British pounds.

### **Interest Income**

For the three-month period ended March 31, 2023, the Company recorded interest income of \$148 compared to \$83 during the same period in prior year. The increase is largely related to an increase in interest rates being earned on cash balances.

For the year ended March 31, 2023, the Company recorded interest income of \$603 compared to \$241 during the same period in prior year. The increase is largely related to an increase in interest rates being earned on cash balances.

### **Contingent consideration accretion**

For the three and twelve month periods ended March 31, 2023 and 2022, the contingent consideration accretion related to the commitments to the former shareholders of Adelia based on milestone achievements (see “Acquisitions”). As of March 31, 2023, all of the milestones related to the Adelia Transaction had been achieved.

### **Change in fair value of contingent consideration**

For the three and twelve month periods ended March 31, 2023 and 2022, the Company recorded a change in fair value related to the achievement of certain milestones in connection with the Adelia Transaction (see “Acquisitions”). The amount recorded represents the difference between the fair value of the contingent consideration determined as at the different reporting periods. As of March 31, 2023, all of the milestones related to the Adelia Transaction had been achieved.

## ***COVID-19 Pandemic***

### ***General***

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a pandemic. Since the outbreak of COVID-19, the Company has focused its efforts on safeguarding the health and well-being of its employees, consultants and community members. To help slow the spread of COVID-19, the Company’s employees have been working remotely, where possible, and abiding by local and national guidance put in place in Canada, the United States, and the UK related to social distancing and restrictions on travel outside of the home. The Company has and will continue to abide by the protocols within Canada, the United States, and the UK regarding the performance of work activities.

## Impact on the Company

During the year ended March 31, 2023, the Company has not experienced any material negative effect on its financial position as a result of COVID-19. Certain operating expenses of the Company, such as those relating to travel and office expenses, have been less than they would have been without the restrictions relating to COVID-19.

The duration and the eventual impact of the spread of COVID-19 remains unknown. In particular, it is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company. To date, a number of businesses have suspended, scaled back or otherwise adjusted their operations and development as cases of COVID-19 have been confirmed, for precautionary purposes or as governments have declared a state of emergency or taken other actions. In the event that the operations or development of the Company are suspended, scaled back or otherwise adjusted, or if the Company's supply chains are disrupted, such events may have a material adverse effect on the Company. The Company may also experience delays in operation of its clinical trials due to slower administrative processes and response times, delayed patient recruitments, and delayed governmental approvals of import and export requests caused by the spread of COVID-19 and the related restrictions. The breadth of the impact of the spread of COVID-19 on investors, businesses, the global economy and financial and commodity markets may also have a material adverse effect on the Company.

The Company raised capital pursuant to the Company's final prospectus dated February 1, 2021 (the "**February 2021 Prospectus**"), the Company's prospectus supplement dated July 28, 2021 (the "**2021 Prospectus Supplement**"), to the short form base shelf prospectus, dated July 5, 2021 (the "**Base Prospectus**"). In addition, the Company is currently raising capital through its ATM Program which is qualified by way of a prospectus supplement dated August 8, 2022, to the Base Prospectus, and pursuant to the LPC Purchase Agreement (defined below), which is qualified by way of a prospectus supplement dated May 30, 2023 to the Base Prospectus. to continue to support its strategic plan. The Company is focused on research and has not seen any major changes to its ability to complete those activities. The Company intends to assess its business and operational needs, and implement cost reductions as needed. The Company is currently focused on the research stage of its projects and will not be generating significant revenues in the short term. In the long term, increases in COVID-19 cases may impact operations, labs and research materials, and result in local lockdowns, shutdowns or slowdowns where the Company completes its research or operations, which may delay timelines in achieving its milestone accordingly. The Company will mitigate any short-term limitations imposed by COVID-19 on materials, research or operations by working with its suppliers and consultants to determinate alternative vendors, suppliers or sources when applicable or available. The Company believes it has sufficient working capital after the completion of the Offering to manage its short- and long-term cash flow needs as it continues to invest into its intellectual property.

## Liquidity, Capital Resources and Cash Flows

	Three Months ended March 31,		Change		Year ended March 31,		Change	
(Canadian dollars in thousands)	2023	2022	\$	%	2023	2022	\$	%
Net cash used in operating activities	(10,838)	(9,721)	(1,117)	11 %	(47,431)	(45,207)	(2,224)	5 %
Net cash used in investing activities	(218)	(121)	(97)	80 %	(3,309)	(770)	(2,539)	330 %
Net cash from financing activities	5,145	68	5,077	7466 %	13,564	35,777	(22,213)	(62)%
Decrease in cash	(5,911)	(9,774)	3,863	(40)%	(37,176)	(10,200)	(26,976)	264 %
Net foreign exchange difference	33	(165)	198	(120)%	168	(185)	353	(191)%
Cash and cash equivalents, beginning of period	22,511	65,580	(43,069)	(66)%	53,641	64,026	(10,385)	(16)%
Cash and cash equivalents, end of period	16,633	55,641	(39,008)	(70)%	16,633	53,641	(37,008)	(69)%

	Three Months ended March 31	Year ended March 31
<b>Net cash used in operating activities</b>	<p>Primarily relates to cash used for operating expenses including research and development expenses, salaries, and other general and administration expenses. Cash flows from operating activities exclude expenses not affecting cash, such as share based compensation expense, depreciation, unrealized foreign exchange gains or losses, and net changes in non-cash balances relating to operations.</p> <p>For the three-month period ended March 31, 2023, cash used in operating activities was \$10,838 driven by a net loss for the period of \$13,720 and an unrealized foreign exchange gain of \$4, partially offset by the following non-cash items: a decrease in working capital of \$2,212, share-based compensation of \$481, net loss on financial instruments measured at fair value through profit or loss of \$125 and depreciation and amortization of \$68.</p>	<p>For the year ended March 31, 2023, cash used in operating activities was \$47,431 driven by a net loss for the period of \$47,490, unrealized foreign exchange gain of \$4,025, an increase in working capital of \$1,437, and non-cash interest income of \$18, partially offset by the following non-cash items: share-based compensation of \$4,686, change in fair value of contingent consideration of \$329, depreciation and amortization of \$251, net loss on financial instruments measured at fair value through profit or loss of \$260, and contingent consideration accretion of \$13.</p>
<b>Net cash used in investing activities</b>	<p>For the three-month period ended March 31, 2023, cash flows were driven by the purchase of intangible assets of \$218.</p>	<p>For the year ended March 31, 2023, cash flows were mainly driven by the purchase of intangible assets, including the exclusive licensing agreement with Mindset and the Asset Acquisition, of \$3,167 and the purchase of equipment of \$142.</p>
<b>Net cash from financing activities</b>	<p>For the three-month period ended March 31, 2023, cash flows from financing activities were related to net proceeds from issuance of Common Shares, through the ATM Program, of \$5,145.</p>	<p>For the year ended March 31, 2023, cash flows from financing activities were related to net proceeds from issuance of Common Shares, through the ATM Program, of \$13,202 and \$362 related to the exercise of warrants.</p>

On August 8, 2022, the Company established an ATM Program that allows the Company to issue and sell up to US\$35,000 of Common Shares in the capital of the Company from treasury to the public, from time to time. Distributions of Common Shares under the ATM Program will be made pursuant to the terms and conditions of the Distribution Agreement. The ATM Program will be effective until the earlier of the issuance and sale of all of the Common Shares issuable pursuant to the ATM Program and August 5, 2023 unless earlier terminated in accordance with the terms of the Distribution Agreement. The Company is not obligated to make any sales of Common Shares under the ATM Program and there can be no assurance as to when such sales will be completed, if ever. The volume and timing of distributions under the ATM Program, if any, will be determined in Cybin's sole discretion and in accordance with the Distribution Agreement. As any Common Shares distributed under the ATM Program will be issued and sold at the prevailing market price at the time of the applicable sale, prices may vary among purchasers through the duration of the ATM Program. As at March 31, 2023, the Company had sold 20,754,120 Common Shares under the ATM Program at an average price of US\$0.5079 per Common Share, for aggregate gross proceeds of US\$10,541.

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.

As at March 31, 2023, the Company had working capital of \$17,522. The Company is a pre-operative stage as it researches and develops its IP portfolio in anticipation of manufacturing in the near future. Therefore the Company will not be able to generate sufficient amounts of cash and cash equivalents from its operations in the short term.

On February 22, 2023, the Company announced a streamlining plan aimed at maximizing the Company's operating efficiency and to allow the Company to focus on critical clinical trials. The Company released approximately 15% of its workforce that previously held roles that were not of a clinical priority or were not directly involved with any of the Company's clinical trial initiatives.

The Company intends to continue to advance its non revenue generating programs over the next twelve to twenty-four months. These intended advancements, along with the expectation of operating at a loss for at minimum the next 12 months, will diminish the Company's working capital. As such, further financings may be required to develop the Company's pipeline, make acquisitions, meet ongoing obligations, and discharge its liabilities in the normal course of business. There is no assurance that additional funds can be raised upon terms acceptable to the Company, or at all, as funding for small companies remains challenging.

The Company's ability to access both public and private capital is dependent upon, among other things, general market conditions and the capital markets generally, market perceptions about the Company and its business operations, and the trading prices of the Company's securities from time to time. When additional capital is required, the Company intends to raise funds through the issuance of equity or debt securities. Other possible sources include the exercise of stock options and warrants of the Company. There can be no assurance that additional funds can be raised upon terms acceptable to the Company, or at all, as funding for early-stage companies remain challenging generally. Given the nature of the Company's business as of the date of this MD&A, and in particular, the fact that its operations are undertaken exclusively within a foreign jurisdiction, the Company may face difficulty in accessing traditional sources of financing, notwithstanding that its business operations are conducted in a regulatory environment within which the Company's activities are neither illegal nor subject to conflicting laws.

The Company's current expenditure obligations include commitments for those projects described in the section entitled "*Major Objectives*" in this MD&A. The Company expects to continue funding these projects with available cash and cash equivalents, and therefore, is subject to risks including, but not limited to, an inability to raise additional funds through debt and/or equity financing to support the Company's continued development, including capital expenditure requirements, operating requirements and to meet its liabilities and commitments as they become due.

The Company constantly monitors and manages its capital resources to assess the liquidity necessary to fund operations and capacity expansion. As at March 31, 2023, the Company had a cash balance of \$16,633 and current liabilities of \$5,663. The Company's current resources are sufficient to settle its current liabilities.

Management continues to raise the capital necessary to become a fully operational enterprise.

The Company has negative cash flow from operating activities and has historically incurred net losses. To the extent that the Company has negative operating cash flows in future periods, it may need to deploy a portion of its existing working capital to fund such negative cash flows. The Company will be required to raise additional funds through the issuance of additional equity securities, through loan financing, or other means, such as through partnerships with other companies and research and development reimbursements. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favourable to the Company as those previously obtained.

The Company's primary capital needs are funds to advance its research and development activities and for working capital purposes. These activities include staffing, preclinical studies, clinical trials and administrative costs. The Company has experienced operating losses and cash outflows from operations since incorporation and will require ongoing financing to continue its research and development. As the Company has not yet achieved profitability, there are uncertainties regarding its ability to continue as a going concern. The Company has not earned any revenue or reached successful commercialization of any products. The Company's success is dependent upon the ability to finance its cash requirements to continue its activities. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favourable to the Company as those previously obtained, or at all. See "Risk Factors".

The Company raised capital pursuant to the February 2021 Prospectus, under which the Company issued 15,264,000 units of the Company (each, a "Unit") at a price of \$2.25 per Unit for aggregate gross proceeds of \$34,304, and pursuant to the July Prospectus Supplement, under which the Company issued 10,147,600 Common Shares at a price of \$3.40 per Common Share for aggregate gross proceeds of \$34,502. In addition, the Company is currently raising capital through its ATM Program, to continue to support its strategic plan. As at March 31, 2023, the Company had sold 20,754,120 Common Shares under the ATM Program at an average price of US\$0.5079 per Common Share, for aggregate gross proceeds of US\$10,541. The Company is also currently raising capital pursuant to the LPC Purchase Agreement. The Company is focused on research and has not seen any major changes to its ability to complete those activities. The Company intends to assess its business and operational needs, and implement cost reductions as needed. The Company is currently focused on the research stage of its projects and will not be generating significant revenues in the short term. In the long term if increased delays in COVID-19 cases may impact labs, research materials, local lockdowns and other shutdowns where the Company completes its research activities, this may delay timelines in achieving its milestone accordingly. The Company will mitigate any short-term limitations imposed by COVID-19 on materials, research or operations by working with its suppliers and consultants to determinate alternative vendors, suppliers or sources when applicable or available. The Company believes it has sufficient working capital after the completion of the Offering to manage its short- and long-term cash flow needs as it continues to invest into its intellectual property.

### *Contractual obligations and commitments*

As at March 31, 2023, the Company had also entered into agreements for various studies which may require the Company to spend up to an additional \$12,074. The Company expects to pay this amount within the next 12 months, however the timing and certainty of the payments are contingent on availability of materials and successful completion of certain milestones. The Company has the right to cancel the studies at its discretion, in which case a cancellation fee may apply, however the Company is not liable to pay the full amount of the study.

In addition to the above, the Company has entered into an exclusive license agreement with Mindset to acquire an extensive targeted class of tryptamine-based molecules. Upon the successful completion of certain milestones contemplated in the agreement, the Company may have to pay additional consideration of up to US\$9,500. At the sole discretion of Cybin, the milestones may be paid in cash or in Common Shares, or a combination thereof, subject to the approval of the Neo Exchange Inc. There is no assurance that the aforementioned milestones will be met.

The Company is party to certain employee and management contracts that contain severance obligations. These contracts contain clauses requiring additional payments to be made upon the occurrence of involuntary termination. As the likelihood of these events taking place is not determinable, no contingent liabilities have been recorded in the consolidated financial statements.

In the normal course of business, the Company may be subject to legal proceedings and claims. As at March 31, 2023, there was no ongoing litigation and therefore no contingent liabilities have been recorded.

### **Outstanding share data**

The table below sets out the outstanding share capital of the Company as at March 31, 2023 and as of the date of this MD&A:

<b>Class of Security</b>	<b>As of March 31, 2023</b>	<b>As of the date of this MD&amp;A</b>
Common Shares	195,328,733	208,325,846
Stock options	29,569,800	29,385,425
Underwriters Warrants	868,740	868,740
Common Share purchase warrants	23,230,485	23,230,485
Class B Shares (as defined below) <sup>(1)</sup>	530,542.1	530,542.1

Note:

(1) The Class B Shares are exchangeable for Common Shares, on the basis of 10 Common Shares for each Class B Share, at the option of the holder thereof, subject to customary adjustments.

## *Common Shares*

The authorized capital of the Company consists of an unlimited number of Common Shares without par value and an unlimited number of preferred shares. As of March 31, 2023, 195,328,733 Common Shares were outstanding and no preferred shares were issued and outstanding. As of the date of this MD&A, 208,325,846 Common Shares are outstanding (see "Subsequent Events").

## *Stock Options*

As of March 31, 2023, options to purchase up to 29,569,800 Common Shares were outstanding under Cybin's equity incentive plan. As of the date of this MD&A, options to purchase up to 29,385,425 Common Shares were outstanding under Cybin's equity incentive plan.

## *Underwriter's Warrants*

As of March 31, 2023 and as of the date of this MD&A, underwriter's warrants to purchase up to 868,740 units of the Company at an exercise price of \$2.25 per unit are outstanding, with each unit consisting of one Common Share and one half of one Common Share purchase warrants, with each Common Share purchase warrant being exercisable to acquire one Common Share at an exercise price of \$3.25 per Common Share for a period of 36 months.

## *Common Share Purchase Warrants*

As of March 31, 2023 and as of the date of this MD&A, warrants to purchase up to 23,230,485 Common Shares were outstanding, exercisable at weighted average exercise price of \$1.29 per Common Share.

## *Class B Shares*

In connection with the Adelia Transaction (see "Acquisitions"), Cybin U.S. (a subsidiary of the Company) has issued 868,833 Class B Shares. The Class B Shares are exchangeable at the holder's option for Common Shares on the basis of 10 Common Shares for 1 Class B Share, subject to customary adjustments. As of March 31, 2023 and as of the date of this MD&A, 530,542.1 Class B Shares were outstanding.

## *Acquisitions*

On December 4, 2020, Cybin entered into a contribution agreement, as amended on September 24, 2021, (the "**Contribution Agreement**") with Cybin Corp., Cybin U.S. (the "**Acquiror**"), a newly formed fully-controlled subsidiary of Cybin created for the purposes of the Adelia Transaction, and all of the shareholders of Adelia (the "**Adelia Shareholders**") whereby the Acquiror has agreed to purchase from the Adelia Shareholders all of the issued and outstanding common shares of Adelia (the "**Adelia Shares**") in exchange for non-voting Class B common shares in the capital of the Acquiror (the "**Class B Shares**"). The Adelia Transaction closed on December 14, 2020 (the "**Closing**").

Pursuant to the Contribution Agreement, the Adelia Shareholders contributed all of the Adelia Shares to the Acquiror as a capital contribution in exchange for the Acquiror issuing to them, in the aggregate, 868,833 Class B Shares in accordance with their respective pro rata percentages at a price per Class B Share equal to \$12.40 (approximately US\$9.69). The aggregate value of the Class B Shares to be issued to the Adelia Shareholders on the Closing was \$19,549 (approximately USD\$15.28 million).

The Class B Shares issued by the Acquiror to the Adelia Shareholders are exchangeable for Common Shares on a 10 Common Shares for 1 Class B Share basis, at the option of the holder thereof, subject to customary adjustments. The purpose of issuing exchangeable Class B Shares to the Adelia Shareholders is to allow the Adelia Shareholders to defer a taxable event, which occurs on the exchange of shares of a United States company for the shares of a Canadian company. Notwithstanding the foregoing, no Class B Shares were exchangeable prior to the first anniversary of the Closing and not more than: (i) 33 1/3% of the Class B Shares were exchangeable prior to the second anniversary of Closing; (ii) 66 2/3% of the Class B Shares were exchangeable prior to the third anniversary of Closing; and (iii) thereafter, 100% of the Class B Shares will be exchangeable ((i), (ii) and (iii), collectively, the "Hold Periods"). The Class B Shares issued to the Adelia Shareholders upon the Closing are exchangeable for a total of 8,688,330 Common Shares, resulting in an effective issue price of \$1.24 per Cybin Share.

On the occurrence of certain milestones as set out in the Contribution Agreement (each a “**Milestone**”), the Acquiror will issue to the Adelia Shareholders in accordance with their pro rata percentage, within five business days following the relevant date at which there is agreement as to the achievement of the Milestone (the “**Milestone Determination Date**”), such number of Class B Shares as shall be determined by dividing the applicable Milestone consideration, as set out in the Contribution Agreement (or where some, but not all, of such sub-Milestone’s in the relevant fiscal quarter are achieved, such lesser portion of such milestone consideration) as is determined in accordance with applicable Milestone, by the greater of: (i) \$0.75; (ii) the 10 day volume weighted average trading price of the Common Shares on the Exchange (or, in the event that the Common Shares are no longer traded on the Exchange, such other nationally recognized exchange as the Common Shares may at the applicable time be trading); and (iii) the closing market price of the Common Shares on the Exchange (or, in the event that the Common Shares are no longer traded on the Exchange, such other nationally recognized exchange as the Common may at the applicable time be trading) in each case, on the close of business on the last business day preceding the Milestone Determination Date. If a particular Milestone has not been achieved by the close of the quarter immediately following the quarter in which such Milestone is scheduled for completion pursuant to the Contribution Agreement, the Acquiror’s obligation to issue Class B Shares on the occurrence of the applicable Milestone shall expire. The total value of the Class B Shares issuable pursuant to the Milestones is up to \$9,388 (approximately US\$7.33 million). As of the date of this MD&A, all of the Milestones have been completed, 1,591,625.3 Class B Shares have been issued, and 1,061,083.2 Class B Shares have been exchanged into Common Shares. Pursuant to the Contribution Agreement, Cybin, the Acquiror and the Adelia Shareholders also entered into a support agreement dated December 14, 2020 (the “**Support Agreement**”), which for the purpose of Canadian securities law, is deemed a “security” as it is a document evidencing an interest in or to a security (i.e. the Common Shares), and, as such, constitutes a security of Cybin. Upon the signing of the Support Agreement, given that each of the Adelia Shareholders are an “accredited investor”, the prescribed restricted period (of (4) months and one (1) day after the date of issuance) as required under Canadian securities law on the Common Shares (which are exchangeable for Class B Shares at a future date) will commence. Therefore, upon the exchange of the Class B Shares for the Common Shares, subject to the Hold Periods, such Common Shares will no longer be within a restrictive period as prescribed under applicable securities law and free trading securities.

On January 11, 2021, the Company announced the achievement of the first Milestone for the period commencing November 15, 2020, as contemplated by the terms of the Contribution Agreement. The achievement included the successful synthesis of multiple tryptamine derivatives in sufficient quantities to initiate in vitro “Proof of Principle”; establish a ADME/PK has been completed; and to demonstrate “In Vitro” ADME “Proof of Principle” that specific synthesis modifies the metabolism of a psychedelic tryptamine. Pursuant to the terms of the Contribution Agreement, an aggregate of 51,163 Class B Shares were issued to the Adelia Shareholders in satisfaction of \$1,018 due to them upon meeting such Milestones.

On March 9, 2021, the Company announced the achievement of certain Milestones for the period commencing January 1, 2021, as contemplated by the terms of the Contribution Agreement. The achievement included API Synthesis and optimization to demonstrate that two or more deuterated tryptamines show significant in vivo modifications of PK consistent with proof of concept, nomination of two deuterated candidates for full IND enabling studies, and completion of a certain API Manufacturing Contract. Pursuant to the terms of the Contribution Agreement, an aggregate of 42,247.3 Class B Shares were issued to the Adelia Shareholders in satisfaction of \$686 due to them upon meeting such Milestones.

On June 28, 2021, Adelia completed the remaining requirements of the second Milestone as listed in the Contribution Agreement. Accordingly, 15,777.1 Class B Shares were issued to the Adelia Shareholders, amounting to \$458. The Class B Shares are exchangeable for a total of 157,771 Common Shares, representing an effective issue price of \$2.90 per Common Share.

On August 17, 2021, an additional 18,788.5 Class B Shares were issued to the Adelia Shareholders due to the achievement of certain requirements of the third and fourth Milestones, amounting to \$633. The Class B Shares are exchangeable for a total of 187,886 Common Shares, representing an effective issue price of \$3.37 per Common Share.

On August 31, 2021, the remaining requirements of the third Milestone were achieved. Accordingly, 9,392.6 Class B Shares were issued to the Adelia Shareholders, amounting to \$317. The Class B Shares are exchangeable for a total of 93,926 Common Shares, representing an effective issue price of \$3.38 per Common Share.



On November 18, 2021, an additional 28,903 Class B Shares were issued to the Adelia Shareholders due to the achievement of certain requirements of the fourth and fifth Milestones, amounting to \$706. These Class B Shares are exchangeable for a total of 289,030 Common Shares, representing an effective issue price of \$2.44 per Common Share.

On November 29, 2021, an additional 31,721.5 Class B Shares were issued to the Adelia Shareholders due to the achievement of certain requirements of the fourth and fifth Milestones, amounting to \$629. These Class B Shares are exchangeable for a total of 317,215 Common Shares, representing an effective issue price of \$1.98 per Common Share.

On January 6, 2022, an additional 15,611.4 Class B Shares were issued to the Adelia Shareholders due to the achievement of the Milestone identified as Year 2 Q1 (v), as contemplated by the terms of the Contribution Agreement, amounting to \$236. These Class B Shares are exchangeable for a total of 156,114 Common Shares, representing an effective issue price of \$1.51 per Common Share.

On February 14, 2022, an additional 41,028.2 Class B Shares were issued to the Adelia Shareholders due to the achievement of the Milestones identified as Y1, Q4 (iv), Y1, Q4 (v) and Y2, Q1 (vi), as contemplated by the terms of the Contribution Agreement, amounting to \$551 at a price per Class B Share of \$13.43. These Class B Shares are exchangeable for a total of 410,282 Common Shares, representing an effective issue price of \$1.34 per Common Share.

On February 18, 2022, an additional 17,239.5 Class B Shares were issued to the Adelia Shareholders due to the achievement of certain Milestones identified as Y2, Q2 (iii), as contemplated by the terms of the Contribution Agreement, having an aggregate value of \$233 at a price per Class B Share of \$13.54. These Class B Shares are exchangeable for a total of 172,395 Common Shares, representing an effective issue price of \$1.35 per Common Share.

On March 25, 2022, an additional 90,546.0 Class B Shares were issued to Adelia Shareholders due to the achievement of certain Milestones identified as Year 1 Q4 (vi); Year 2 Q2 (ii); Year 2 Q2 (v) and Year 2, Q3 (iii), as contemplated by the terms of the Contribution Agreement, having an aggregate value of \$905 at a price per Class B Share of \$9.994. These Class B Shares are exchangeable for a total of 905,460 Common Shares, representing an effective issue price of \$1.00 per Common Share.

On April 1, 2022, an additional 22,428.3 Class B Shares were issued to Former Adelia Shareholders due to the achievement of the Milestone identified as Year 2 Q2 (iv), as contemplated by the terms of the Contribution Agreement, having an aggregate value of \$229 at a price per Class B Share of \$10.20. These Class B Shares are exchangeable for a total of 224,283 Common Shares, representing an effective issue price of \$1.02 per Common Share. In consideration for the Milestone achieved, on June 22, 2022, an additional 456.5 Class B shares having an aggregate value of \$5 were issued to Former Adelia Shareholders.

On June 24, 2022, an additional 266,933.1 Class B Shares were issued to Former Adelia Shareholders due to the achievement of certain Milestones identified as Y2, Q2 (i), (vi), Y2, Q3 (ii), Year 2 Q4 (i) and Year 3 Q1 (i), (ii), (iii), as contemplated by the terms of the Adelia Contribution Agreement, having an aggregate value of \$2,034 at a price per Class B Share of \$7.62. These Class B Shares are exchangeable for a total of 2,669,331 Common Shares, representing an effective issue price of \$0.762 per Common Share.

On June 27, 2022, an additional 37,366.2 Class B Shares were issued to Former Adelia Shareholders due to the achievement of the Milestone identified as Y2, Q3 (i), as contemplated by the terms of the Adelia Contribution Agreement, having an aggregate value of \$280 at a price per Class B Share of \$7.50. These Class B Shares are exchangeable for a total of 373,662 Common Shares, representing an effective issue price of \$0.75 per Common Share.

On August 31, 2022, an additional 33,190.1 Class B Shares were issued to Former Adelia Shareholders due to the achievement of the Milestone identified as Y2, Q4 (ii), as contemplated by the terms of the Adelia Contribution Agreement, having an aggregate value of \$468 at a price per Class B Share of \$14.10. These Class B Shares are

exchangeable for a total of 331,901 Common Shares, representing an effective issue price of \$1.41 per Common Share.

As of August 31, 2022, all of the Milestones contemplated by the terms of the Adelia Contribution Agreement were successfully achieved. The Milestones focused on bringing Cybin's psychedelic programs from the lab to the clinic. As Cybin has advanced its research and development pipeline, these milestone achievements have contributed to discovering potential new drug formulations and delivery methods, creating clinical protocols for psychedelic compounds, and most recently, supporting clinical-stage development of the Company's CYB003 and CYB004 programs for MDD and anxiety disorders, respectively.

Pursuant to the Contribution Agreement certain members of Adelia entered into advisory and/or executive employment arrangements with Cybin upon the Closing and, in such capacity, received, in the aggregate, a grant of options to purchase up to 2,244,100 to acquire Common Shares, pursuant to Cybin's equity incentive plan, exercisable for a period of five (5) years and subject to vesting, at an exercise price of \$1.74 per Cybin Share. An additional 555,900 options to acquire Common Shares were issued to eligible participants at the direction of the Adelia Shareholders following the Closing.

### ***Off-balance sheet arrangements***

As at March 31, 2023 and the date of this MD&A, other than these contractual obligations and commitments disclosed in note 13 of the Financial Statements, the Company does not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the results of operations or financial condition of the Company.

### ***Transactions between related parties***

For the three and twelve-month periods ended March 31, 2023, the key management personnel of the Company were the board of directors of the Company (the "**Board**"), the Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Chief Growth Officer, Chief Compliance, Ethics & Administrative Officer, Chief Legal Officer, Chief Innovation Officer, Chief Medical Officer, and Chief Scientific Officer.

Compensation for key management personnel of the Company for the three month and twelve-month periods ended March 31, 2023 consisted of consulting fees, short term benefits and other compensation of \$1,952 and \$8,315, respectively (three and twelve-month periods ended March 31, 2022 - \$4,395 and \$15,491).

### ***Critical accounting estimates***

The preparation of the Company's Financial Statements requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting year. Actual outcomes could differ from these estimates. The consolidated financial statements include estimates which, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the consolidated financial statements and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the year in which the estimate is revised and future years if the revision affects both current and future years. These estimates are based on historical experience, current and future economic conditions and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

Information about significant judgements and estimates used in applying accounting policies that have the most significant effect on the amounts recognized in the Company's consolidated financial statements relate to:

### ***Ability to continue as a going concern***

In order to assess whether it is appropriate for the Company to continue as a going concern, management is required to apply judgment and make estimates with respect to future cash flow projections.

In arriving at this judgment, there were a number of assumptions and estimates involved in calculating these future cash flow projections. This includes making estimates regarding the timing and amounts of future expenditures and the ability and timing of raising additional financing.

### **Business combinations**

A business combination is a transaction or event in which an acquirer obtains control of one or more businesses and is accounted for using the acquisition method. The total consideration paid for the acquisition is the aggregate of the fair values of assets given, liabilities incurred or assumed, and equity instruments issued in exchange for control of the acquiree at the acquisition date. The acquisition date is the date where the Company obtains control of the acquiree. The identifiable assets acquired and liabilities assumed are recognized at their acquisition date fair values, except for deferred taxes and share-based payment awards where IFRS provides exceptions to recording the amounts at fair value. Acquisition costs are expensed to profit or loss.

Contingent consideration is measured at its acquisition-date fair value and included as part of the consideration transferred in a business combination. Contingent consideration that is classified as equity is not remeasured at subsequent reporting dates and its subsequent settlement is accounted for within equity. Contingent consideration that is classified as an asset or a liability is remeasured at subsequent reporting dates in accordance with IFRS 9, or IAS 37 Provisions, Contingent Liabilities and Contingent Assets, as appropriate, with the corresponding gain or loss being recognized in profit or loss.

Non-controlling interest in the acquiree, if any, is recognized either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets, determined on an acquisition-by-acquisition basis. For each acquisition, the excess of total consideration, the fair value of previously held equity interest prior to obtaining control and the non-controlling interest in the acquiree, over the fair value of the identifiable net asset acquired, is recorded as goodwill.

Certain fair values may be estimated at the acquisition date pending confirmation or completion of the valuation process. Where provisional values are used in accounting for a business combination, they may be adjusted retrospectively in subsequent periods. The measurement period is the period from the acquisition date to the date complete information about facts and circumstances that existed as of the acquisition date is received. However, the measurement period does not exceed one year from the acquisition date.

Acquisitions that do not meet the definition of a business combination are accounted for as an asset acquisition. Consideration paid for an asset acquisition is allocated to the individual identifiable assets acquired and liabilities assumed based on their relative fair values.

### **Share based payments**

The fair value of share-based compensation expenses are estimated using the Black-Scholes option pricing model and rely on a number of estimates, such as the expected life of the option, the volatility of the underlying share price, the risk-free rate of return, and the estimated rate of forfeiture of options or warrants granted.

### **Impairment of non-financial assets**

Impairment exists when the carrying value of an asset or cash generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The fair value less costs of disposal calculation is based on available data from binding sales transactions, conducted at arm's length, for similar assets or observable market prices less incremental costs of disposing of the asset. The value in use calculation is based on a discounted cash flow ("DCF") model. The cash flows are derived from the forecast for the next ten years and do not include restructuring activities that the Company is not yet committed to or significant future investments that will enhance the performance of the assets of the CGU being tested. The determination of the Company's CGUs is based on management's judgement. The recoverable amount is sensitive to the discount rate used for the DCF model as well as the expected future cash-inflows and the growth rate used for extrapolation purposes. These estimates are most relevant to goodwill and other intangibles with indefinite useful lives recognized by the Company. Future events could cause the assumptions used in the impairment review to change with a consequential adverse effect on the results of the Company.

## **Income Taxes**

The Company computed an income tax provision in accordance with the applicable income tax laws. However, actual amounts of income tax expense only become final upon filing and acceptance of the tax return by the relevant authorities, which occurs subsequent to the issuance of the consolidated financial statements. Additionally, estimation of income taxes includes evaluation the recoverability of deferred tax assets based on an assessment of the ability to use the underlying future tax deductions before they expire against future taxable income. The assessment is based upon existing tax laws and estimates of future taxable income. The income tax provision is based on estimates of full-year earnings by jurisdiction. The average annual effective income tax rates are re-estimated at the end of each reporting period. To the extent that estimates and forecasts differ from actual results, adjustments are recorded in subsequent periods.

### ***Summary of significant accounting policies***

Disclosure regarding the Company's significant accounting policies are set out in Note 2, *Significant Accounting Policies and Basis of Preparation* in the Financial Statements. This MD&A should be read in conjunction with the Financial Statements. Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Financial Statements.

### ***Disclosure controls and procedures***

In accordance with the requirements of National Instrument 52-109–Certification of Disclosure in Issuers' Annual and Interim Filings, the Company's management, including the Company's Chief Executive Officer (the "CEO") and the Company's Chief Financial Officer (the "CFO"), have evaluated the effectiveness of the Company's disclosure controls and procedures. Based upon the results of the evaluation, the CEO and the CFO have concluded that as at March 31, 2023, the Company's disclosure controls and procedures to provide reasonable assurance that the information required to be disclosed by the Company in reports it files is recorded, processed, summarized and reported within the appropriate time periods and forms were effective.

### ***Internal Control over Financial Reporting***

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with applicable IFRS. Internal control over financial reporting should include those policies and procedures that establish the following:

- maintenance of records in reasonable detail, that accurately and fairly reflect the transactions and dispositions of assets;
- reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with applicable IFRS;
- receipts and expenditures are only being made in accordance with authorizations of management or the Board; and
- reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial instruments.

The Company's management, with the participation of the CEO and the CFO, assessed the effectiveness of the Company's internal controls over financial reporting and concluded that as at March 31, 2023, the Company's internal control over financial reporting was effective.

During the period ended March 31, 2023, the Company did not make any significant changes to its internal controls over financial reporting that would have materially affected, or reasonably likely to materially affect, its internal controls over financial reporting.

## ***Limitations of Disclosure Controls and Procedures and Internal Control over Financial Reporting***

The Company's management, including the CEO and the CFO, believe that due to inherent limitations, any disclosure controls and procedures or internal control over financial reporting, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. These inherent limitations include, among other items: (i) that management's assumptions and judgments could ultimately prove to be incorrect under varying conditions and circumstances; (ii) the impact of any undetected errors; and (iii) that controls may be circumvented by the unauthorized acts of individuals, by collusion of two or more people, or by management override. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Accordingly, because of the inherent limitations in a cost effective control system, misstatements due to error or fraud may occur and not be detected.

## ***New accounting standards and interpretations not yet adopted***

### **IAS 1, Presentation of Financial Statements ("IAS 1") - Classification of Liabilities as Current or Non-Current**

In January 2020, the IASB issued amendments to IAS 1. The amendments aim to promote consistency in applying the requirements by helping companies determine whether, in the consolidated statements of financial position, debt and other liabilities with an uncertain settlement date should be classified as current (due or potentially due to be settled within one year) or non-current. The amendments include clarifying the classification requirements for debt a company might settle by converting it into equity. The amendments are effective for annual reporting periods beginning on or after January 1, 2024, with earlier application permitted. The Company is still assessing the impact of adopting these amendments on its consolidated financial statements.

### **Amendments to IAS 1 and IFRS Practice Statement 2**

In February 2021, the IASB issued amendments to IAS 1 and IFRS Practice Statement 2, Making Materiality Judgements, in which it provides guidance and examples to help entities apply materiality judgements to accounting policy disclosures. The amendments aim to help entities provide accounting policies disclosures that are more useful by replacing the requirement for entities to disclose "significant" accounting policies with a requirement to disclose their "material" accounting policies and adding guidance on how entities apply the concept of materiality in making decisions about accounting disclosures. The amendments to IAS 1 are applicable for annual periods beginning on or after January 1, 2023 with earlier application permitted. Since the amendments to IFRS Practice Statement 2 provide non-mandatory guidance on the application of the definition of material to accounting policy information, an effective date for these amendments is not necessary. The amendments are not expected to have a material impact on the Company's consolidated financial statements.

### **IAS 8, Accounting Policies, Changes in Accounting Estimates and Errors ("IAS 8") - Definition of Accounting Estimates**

In February 2021, the IASB amendments to IAS 8. The amendment will require the disclosure of material accounting policy information rather than disclosing significant accounting policies and clarifies how to distinguish changes in accounting policies from changes in accounting estimates. Under the new definition, accounting estimates are "monetary amounts in financial statements that are subject to measurement uncertainty". The amendment provides clarification to help entities to distinguish between accounting policies and accounting estimates. The amendments are effective for annual periods beginning on or after January 1, 2023. The Company has determined that adoption of these amendments has no significant effect on the Company's consolidated financial statements.

### **IAS 12, Income Taxes ("IAS 12") - Deferred Tax related to Assets and Liabilities Arising from a Single Transaction**

In May 2021, the IASB issued amendments to IAS 12. The amendment narrows the scope of the initial recognition exemption so that it does not apply to transactions that give rise to equal taxable and deductible temporary differences. As a result, companies will need to recognize a deferred tax asset and deferred tax liability for temporary differences arising on initial recognition of transactions such as leases and decommissioning obligations. The amendments are effective for annual reporting periods beginning on or after January 1, 2023 and are to be applied retrospectively. The Company has determined that adoption of these amendments has no significant effect on the Company's consolidated financial statements.

All other IFRSs and amendments issued but not yet effective have been assessed by the Company and are not expected to have a material impact on the Company's consolidated financial statements.

### ***Financial and Risk Management***

The Company is exposed to a variety of financial instrument related risks and is exposed to liquidity risk, credit risk, interest rate risk, foreign exchange risk, equity price risk, asset forfeiture risk and banking risk. Management, in conjunction with the Board, mitigates these risks by assessing, monitoring and approving the Company's risk management processes. See note 15, *Financial Instruments* in the Financial Statements for the Company's financial instruments, financial risk factors, and other instruments. The Company's financial risk activities are governed by the appropriate policy and procedures and financial risks are identified, measured and managed in accordance with the Company's policies and risk appetite.

In addition, the Company noted the following risks specific to the psychedelic industry that it is exposed to:

#### **Liquidity risk**

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company is a development stage company and is reliant on external fundraising to support its operations. Once funds have been raised, the Company manages liquidity risk by continuously monitoring actual and projected cash flows. The board of directors reviews and approves the Company's operating and capital budgets, as well as any material transactions not in the ordinary course of business.

#### **Regulatory risk**

Regulatory risk pertains to the risk that the Company's business objectives are contingent, in part, upon the compliance with regulatory requirements. Due to the nature of the industry, regulatory requirements can be more stringent than other industries and may also be punitive in nature. Any delays in obtaining, or failure to obtain regulatory approvals can significantly delay operational and product development and can have a material adverse effect on the Company's business, results of operation, and financial condition.

The Company routinely monitors regulatory changes occurring in the psychedelic industry at the city, state, and national levels. Although the general regulatory outlook for the psychedelic industry has been moving in a positive direction, unforeseen regulatory changes could have a material adverse effect on the business as a whole.

#### **Currency risk**

The Company is exposed to currency risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of the Company's business transactions and balances denominated in currencies other than the Canadian dollar.

### ***Subsequent Events***

During the period from April 1, 2023 to June 27, 2023, the Company sold an additional 8,533,269 Common Shares, at an average price of US\$0.2896 per Common Share, for aggregate gross proceeds of US\$2,471, through its ATM Program. As of June 27, 2023, the ATM allows Cybin to issue and sell up to an additional US\$21,988 of Common Shares. Depending on market conditions, this will allow Cybin to access additional cash for growth opportunities and working capital.

On May 9, 2023, the Company announced that it had completed dosing for the last subject in Part B of the Phase 1 CYB004-E trial.

On May 24, 2023, the Company announced that it had initiated first-in-human dosing of CYB004 in Part C of the Phase 1 CYB004-E trial.

On May 30, 2023, the Company announced that it has entered into a common share purchase agreement (the "**LPC Purchase Agreement**") with Lincoln Park Capital Fund, LLC ("LPC"). Subject to the terms and conditions of the

LPC Purchase Agreement, the Company has the right to sell, and LPC is obligated to purchase, up to US\$30,000 (approximately \$41,000) of the Company's common shares over a 36-month period at prices that are based on the market price at the time of each sale to LPC. Cybin, in its sole discretion, controls the timing and amount of all sales of common shares under the LPC Purchase Agreement. As of the date of this MD&A, the Company has sold 1,925,000 Common Shares, at an average price of US\$0.2417 per Common Shares, for aggregate gross proceeds of US\$465 pursuant to the LPC Purchase Agreement. As of the date of this MD&A, Cybin is allowed to issue and sell up to an additional US\$29,535 of Common Shares under the LPC Purchase Agreement.

Cybin has the right to terminate the LPC Purchase Agreement at any time at no cost or penalty. LPC has agreed not to engage in any short selling or hedging activity of any kind in the Company's common shares. As consideration for LPC's obligation to purchase common shares from the Company at its direction under the LPC Purchase Agreement, Cybin issued 2,538,844 common shares to LPC as a commitment fee. The Purchase Agreement provides that Cybin may not issue or sell any Common Shares to LPC under the Purchase Agreement which, when aggregated with all other Common Shares then beneficially owned by LPC and its affiliates (as calculated pursuant to Section 13(d) of the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 13d-3 thereunder), would result in LPC beneficially owning more than 9.99% of the outstanding Common Shares.

On June 5, 2023, the Company announced changes to its scientific management team. Following the achievement of the final milestones as contemplated by the terms of the Contribution Agreement, Michael Palfreyman Ph.D. and Brett Greene, who joined the Company following the Adelia Transaction, left their roles as Chief R&D Officer and Chief Innovations Officer, respectively, and transition into advisory roles at the Company. Alex Nivorozhkin Ph.D., one of Adelia's founders, will continue in his role as Chief Scientific Officer of Cybin.

### ***Risk Factors***

In addition to the risks described herein, reference is made to the section entitled "Risk Factors" in the AIF, which is incorporated herein by reference. The risks described herein are not the only risks faced by the Company and security holders of the Company. Additional risks and uncertainties not currently known to the Company, or that the Company currently deems immaterial, may also materially and adversely affect its business. The business, financial condition, revenues or profitability of the Company could be materially adversely affected by any of the risks set forth in this MD&A. The trading price of the Common Shares could decline due to any of these risks and investors could lose all or part of their investment. This MD&A contains forward-looking statements that involve risks and uncertainties. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by the Company described below and elsewhere in this MD&A. No inference should be drawn, nor should an investor place undue importance on, the risk factors that are included in this MD&A as compared to those included in other documents publicly filed by the Company, as all risk factors are important and should be carefully considered by a potential investor.

### **Risks Related to the Company's Business and Industry**

#### ***Novel Coronavirus "COVID-19"***

The outbreak of the novel strain of coronavirus, specifically identified as "COVID-19", resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which included the implementation of travel bans, self-imposed quarantine periods and social distancing, caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets experienced significant volatility and weakness. Governments and central banks reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. Although some of these measures have been amended or repealed, there remains a future risk of reinstated measures in response to the spread of COVID-19.

The duration and impact of the COVID-19 outbreak is unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company and its operating subsidiaries in future periods. However, depending on the length and severity of the spread of COVID-19, this could impact the Company's operations, cause delays relating to approval from Health Canada, the FDA and equivalent organizations in other countries, postpone research activities, and impair the Company's ability to raise funds depending on COVID-19's effect on capital markets.

While the Company is continuously assessing the potential impact of the spread of COVID-19 on its operations, any assessment is subject to extreme uncertainty as to probability, severity and duration. The Company has attempted to assess the impact of the spread of COVID-19 by identifying risks in the following principle areas:

- **Mandatory Closure.** In the period following March 2020, many provinces, states and localities implemented temporary, mandatory shut-downs of businesses to prevent the spread of COVID-19. In the locations where the Company operates or conducts research activity, these activities were deemed an “essential service”, and thus, were not subject to the mandatory closures applicable to non-essential businesses. The Company’s ability to generate revenue and meet its milestones could be materially impacted by any shut-down of operations or services resulting from any future, mandatory closures in response to the spread of COVID-19.
- **Research and Development Disruptions.** The Company relies on a third parties for its research and development activities. If these third parties are unable to continue operating due to mandatory closures or other effects of the spread of COVID-19, it may negatively impact the Company’s ability to meet its milestones and may significantly delay development. At this time, the Company has not experienced any significant disruptions.
- **Staffing Disruption.** The Company is, for the time being, implementing among its staff where feasible “social distancing” measures recommended by local authorities. The Company has cancelled nonessential travel by employees, implemented remote meetings where possible, and permitted all staff who can work remotely to do so. For those whose duties require them to work on-site, measures have been implemented to reduce infection risk, such as reducing contact with patients, mandating additional cleaning and hand disinfection and providing masks and gloves to certain personnel. Nevertheless, despite such measures, the Company may find it difficult to ensure that its operations remain staffed due to employees falling ill with COVID-19 and deciding not to come to work on their own volition to avoid infection.

The Company is actively addressing the risk to business continuity represented by each of the above factors through the implementation of a broad range of measures throughout its structure and is re-assessing its response to the spread of COVID-19 on an ongoing basis. The above risks individually or collectively may have a material impact on the Company’s ability to generate revenue.

The Company has sufficient cash on hand raised via equity financings to fund its operations for the next 12-months and meet its working capital requirements. It is anticipated that the long-term goals of the Company will require additional capital contributions via debt or equity financings. In the event that the impact of COVID-19 worsens and negatively affects capital markets generally, there is a risk that the Company may not be able to secure funding for these long-term objectives.

### ***Limited Operating History***

The Common Shares commenced trading on the Exchange on November 10, 2020 on a post-Reverse Takeover basis and therefore the Company has a limited operating history as a public company. To operate effectively, the Company will be required to continue to implement changes in certain aspects of its business, improve information systems and develop, manage and train management-level and other employees to comply with ongoing public company requirements. Failure to take such actions, or delay in implementation thereof, could adversely affect the business, financial condition, liquidity and results of operations of the Company and, more specifically, could result in regulatory penalties, market criticism or the imposition of cease trade orders in respect of the Common Shares.

The Company will be subject to all of the business risks and uncertainties associated with any new business enterprise, including the risk that it will not achieve its operating goals. In order for the Company to meet future operating and debt service requirements, it will need to be successful in its growth, marketing and sales efforts. Additionally, where the Company experiences increased production and future sales, its current operational infrastructure may require changes to scale its business efficiently and effectively to keep pace with demand and achieve long-term profitability. If the Company’s products and services are not accepted by new customers, the Company’s operating results may be materially and adversely affected.



### ***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 for a prescription drug product candidate may ultimately vary from what is publicly disclosed. See “Commercial Scale Product Manufacturing”, “Safety and Efficacy of Products”, “Clinical Testing and Commercializing Product Candidates”, “Completion of Clinical Trials”, and “Nature of Regulatory Approvals” as discussed under this heading “Risk Factors” 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 the Common Shares.

### ***Speculative Nature of Investment Risk***

An investment in the securities of the Company carries a high degree of risk and should be considered as a speculative investment. The Company has no history of earnings, limited cash reserves, limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future.

### ***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, the EMA 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, FDA or EMA 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.

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 also 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.

### ***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, psilocin, DMT, and 5-Methoxy-DMT, 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. The EU member states currently classify DMT as a Schedule I substance under the UN 71 and, as such, a licence is required to produce, dispense, import or export any Schedule I substances, but the specific requirements vary from country to country. Currently in the Netherlands, DMT is classified as a List 1 Drug under the Dutch Opium Act and, as such, subject to express authorization being obtained, the production, trade and possession of DMT are prohibited. In the United Kingdom, "Fungus (of any kind) which contains psilocin or an ester of psilocin" is controlled as a Class A drug under the MDA and Schedule 1 drug under the MDR. As psilocybin is a phosphate ester of psilocin, even if it is isolated from psilocin, it will still be treated as a Class A drug under the MDA and as a Schedule 1 drug under the MDR. Schedule 1 drugs can only be lawfully manufactured, produced, possessed and supplied under a controlled drugs domestic licence issued by the UK Home Office.

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, the Netherlands, the UK, 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, the EMA or other similar regulatory authorities have not evaluated claims regarding psilocybin, DMT, 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, DMT, 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.

### ***Risks of Operating in European Countries***

The Company is subject to additional risks related to operating in countries in Europe including: (i) differing regulatory requirements in Europe; (ii) unexpected changes in price and exchange controls and other regulatory requirements; (iii) increased difficulties in managing the logistics and transportation of collecting and shipping patient material; (iv) import and export requirements and restrictions; (v) compliance with tax, employment, immigration and labour laws for employees living or traveling abroad; (vi) foreign taxes, including withholding of payroll taxes; (vii) foreign currency fluctuations, which could result in increased operating expenses, and other obligations incident to doing business in another country; (viii) difficulties staffing and managing foreign operations; (ix) potential liability under the Corruption of Foreign Public Officials Act of Canada or comparable foreign regulations; (x) challenges enforcing its contractual and intellectual property rights, especially in those European countries that do not respect and protect intellectual property rights to the same extent as Canada or the United States; (xi) production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and (xii) business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with the Company's international operations may materially adversely affect its ability to attain or maintain profitable operations.

### ***"Foreign Private Issuer" Status Under the U.S. Securities Laws***

The Company is a "foreign private issuer", under applicable U.S. federal securities laws, and is, therefore, not subject to the same requirements that are imposed upon U.S. domestic issuers by the Securities and Exchange Commission ("SEC"). Under the Exchange Act, the Company is subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, the Company does not file the same reports that a U.S. domestic issuer would file with the SEC, although the Company is required to file with or furnish to the SEC the continuous disclosure documents that it is required to file in Canada under Canadian securities laws. In addition, the Company's officers, directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions of Section 16 of the Exchange Act. Therefore, the Company's shareholders

may not know on as timely a basis when the Company's officers, directors and principal shareholders purchase or sell Common Shares, as the reporting periods under the corresponding Canadian insider reporting requirements are longer.

As a foreign private issuer, the Company is exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements. The Company is also exempt from Regulation FD, which prohibits issuers from making selective disclosures of material non-public information. While the Company complies with the corresponding requirements relating to proxy statements and disclosure of material non-public information under Canadian securities laws, these requirements differ from those under the Exchange Act and Regulation FD and shareholders should not expect to receive the same information at the same time as such information is provided by U.S. domestic companies. In addition, the Company may not be required under the Exchange Act to file annual and quarterly reports with the SEC as promptly as U.S. domestic companies whose securities are registered under the Exchange Act.

### ***Plans for Growth***

The Company intends to continue to advance its research and development programs and operations over the next 12 to 24 months. This advancement will place a significant strain on the Company's management systems and resources. The Company may not be able to implement its business strategy in a rapidly evolving market. In particular, the Company may be required to manage multiple relationships with various strategic industry participants and other third parties, which relationships could be strained. Similarly, an increase in the number of third-party relationships the Company has, may lead to management of the Company being unable to manage growth effectively. The occurrence of such events may result in the Company being unable to successfully identify, manage and exploit existing and potential market opportunities.

### ***Limited Products***

The Company will be heavily reliant on the production and distribution of psychedelics and related products. If they do not achieve sufficient market acceptance, it will be difficult for the Company to achieve profitability.

The Company's revenue will be derived almost exclusively from sales of psychedelic pharmaceutical products, and the Company expects that its psychedelic pharmaceutical products will account for substantially all of its revenue for the foreseeable future. If the psychedelic pharmaceutical market declines or psychedelics fail to achieve substantially greater market acceptance than it currently enjoys, the Company will not be able to grow its revenues sufficiently for it to achieve consistent profitability.

Even if products to be distributed by the Company conform to international safety and quality standards, sales could be adversely affected if consumers in target markets lose confidence in the safety, efficacy, and quality of psychedelic pharmaceutical products. Adverse publicity about psychedelic pharmaceutical products that the Company sells may discourage consumers from buying products distributed by the Company.

### ***Limited Marketing and Sales Capabilities***

The Company will, for the immediate future, have limited marketing and sales capabilities, and there can be no assurance that it will be able to develop or acquire these capabilities at the level needed to produce and deliver for sale, through industry partners, its products in sufficient commercial quantities. Further, there can be no assurance that the Company, either on its own or through arrangements with other industry participants, will be able to develop or acquire such capabilities on a cost-effective basis, or at all. Finally, there can be no assurance that the Company's industry partners will be able to market or sell the Company's products in compliance with requisite regulatory protocols or on a cost-effective basis. The Company's dependence upon third parties for the production, and marketing or sale, as applicable, of the Company's products could have a material adverse effect on the Company's business, financial condition and results of operations.

### ***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.

### ***No Profits or Significant Revenues***

The Company has no history upon which to evaluate its performance and future prospects. The Company's proposed operations are subject to all the business risks associated with new enterprises. These include likely fluctuations in operating results as the Company makes significant investments in research, development and product opportunities, and reacts to developments in its market, including purchasing patterns of customers, and the entry of competitors into the market. The Company will only be able to pay dividends on any shares once its directors determine that it is financially able to do so. The Company cannot make any assurance that it will be profitable in the next three years or generate sufficient revenues to pay dividends to the holders of the Common Shares.

### ***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.

### ***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.

### ***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, the FDA and the EMA, 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. 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.

### ***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, the EMA 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 also 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.

### ***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 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.

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, the UK, the Netherlands, 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.

### ***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 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.

### ***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.

### ***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, the FDA and the EMA. 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, the EMA 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, the EMA 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 also 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.

### ***Unfavourable Publicity or Consumer Perception***

The Company believes the psychedelic pharmaceutical industry is highly dependent upon consumer perception regarding the safety, efficacy and quality of psychedelic pharmaceutical products. Consumer perception of the Company's psychedelic pharmaceutical products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention and other publicity regarding the consumption of psychedelics. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favourable to the psychedelic pharmaceutical industry or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention or other publicity that are perceived as less favourable than, or that question, earlier research reports, findings or publicity could have a material adverse effect on the demand for the Company's psychedelic products and the business, results of operations, financial condition and cash flows of the Company. The Company's dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention or other publicity, whether or not accurate or with merit, could have a material adverse effect on the Company, the demand for the Company's psychedelic products, and the business, results of operations, financial condition and cash flows of the Company. Further, adverse publicity reports or other media attention regarding the safety, efficacy and quality of psychedelic products in general, or the Company's psychedelic products and services specifically or associating the consumption of psychedelics with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products legally, appropriately or as directed.

The psilocybin industry is highly dependent upon consumer perception regarding the medical benefits, safety, efficacy and quality of the psilocybin distributed for medical purposes to such consumers. There can be no assurance that future scientific research or findings on the medical benefits, viability, safety, efficacy and dosing of psilocybin or isolated constituents, regulatory proceedings, litigation, media attention or other research findings or publicity will be favourable to the industry or the Company or any particular product, or consistent with earlier publicity.

### ***Social Media***

There has been a recent marked increase in the use of social media platforms and similar channels that provide individuals with access to a broad audience of consumers and other interested persons. The availability and impact of information on social media platforms is virtually immediate and many social media platforms publish user-generated content without filters or independent verification as to the accuracy of the content posted. Information posted about the Company may be adverse to the Company's interests or may be inaccurate, each of which may harm the Company's business, financial condition and results of operations.

## ***Biotechnology and Pharmaceutical Market Competition***

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The Company's competitors include large, well-established pharmaceutical companies, biotechnology companies, and academic and research institutions developing therapeutics for the same indications the Company is targeting and competitors with existing marketed therapies. Many other companies are developing or commercializing therapies to treat the same diseases or indications for which the Company's prescription drug product candidates may be useful. Although there are no approved therapies that specifically target opioid addiction, some competitors use therapeutic approaches that may compete directly with the Company's prescription drug product candidates.

Many of the Company's competitors have substantially greater financial, technical and human resources than the Company does and have significantly greater experience than the Company in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, the Company's competitors may succeed in obtaining regulatory approval for products more rapidly than the Company does. The Company's ability to compete successfully will largely depend on:

- the efficacy and safety profile of its prescription drug product candidates relative to marketed products and other prescription drug product candidates in development;
- the Company's ability to develop and maintain a competitive position in the product categories and technologies on which it focuses;
- the time it takes for the Company's prescription drug product candidates to complete clinical development and receive marketing approval;
- the Company's ability to obtain required regulatory approvals;
- the Company's ability to commercialize any of its prescription drug product candidates that receive regulatory approval;
- the Company's ability to establish, maintain and protect intellectual property rights related to its prescription drug product candidates; and
- acceptance of any of the Company's prescription drug product candidates that receive regulatory approval by physicians and other healthcare providers and payers.

Competitors have developed and may develop technologies that could be the basis for products that challenge the discovery research capabilities of prescription drug product candidates the Company is developing. Some of those products may have an entirely different approach or means of accomplishing the desired therapeutic effect than the Company's prescription drug product candidates and may be more effective or less costly than its prescription drug product candidates. The success of the Company's competitors and their products and technologies relative to the Company's technological capabilities and competitiveness could have a material adverse effect on the future preclinical studies and clinical trials of the Company's prescription drug product candidates, including its ability to obtain the necessary regulatory approvals for the conduct of such clinical trials. This may further negatively impact the Company's ability to generate future product development programs using psychedelic inspired compounds.

If the Company is not able to compete effectively against its current and future competitors, the Company's business will not grow, and its financial condition and operations will substantially suffer.

Further, there can be no assurance that potential competitors of the Company, which may have greater financial, cultivation, production, sales and marketing experience, and personnel and resources than the Company, are not currently developing, or will not in the future develop, products and strategies that are equally or more effective and/or economical as any products or strategies developed by the Company or which would otherwise render the Company's business, products and strategies, as applicable, ineffective, or obsolete. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Company.

## ***Reliance on Key Executives and Scientists***

The loss of key members of the Company's staff, could harm the Company. The Company does not have employment agreements with all members of its staff, although such employment agreements do not guarantee their retention. The Company also depends on its scientific and clinical collaborators and advisors, all of whom have outside commitments

that may limit their availability to the Company. In addition, the Company believes that its future success will depend in large part upon its ability to attract and retain highly skilled scientific, managerial, medical, manufacturing, clinical and regulatory personnel, particularly as the Company expands its activities and seeks regulatory approvals for clinical trials. The Company enters into agreements with its scientific and clinical collaborators and advisors, key opinion leaders and academic partners in the ordinary course of its business. The Company also enters into agreements with physicians and institutions who will recruit patients into the Company's clinical trials on its behalf in the ordinary course of its business. Notwithstanding these arrangements, the Company faces significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. The Company cannot predict its success in hiring or retaining the personnel it requires for continued growth. The loss of the services of any of the Company's executive officers or other key personnel could potentially harm its business, operating results or financial condition.

### ***Employee Misconduct***

Notwithstanding having established an insider trading policy and code of ethics and business conduct (see the AIF for further details), the Company is exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with Health Canada, the FDA and/or the EMA regulations, provide accurate information to Health Canada, the FDA and/or the EMA, comply with manufacturing standards the Company has established, comply with federal and provincial healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to the Company. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to the Company's reputation. If any such actions are instituted against the Company, and the Company is not successful in defending itself or asserting its rights, those actions could have a substantial impact on the Company's business and results of operations, including the imposition of substantial fines or other sanctions.

### ***Business Expansion and Growth***

The Company may in the future seek to expand its pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations, or in-licensing one or more prescription drug product candidates. Acquisitions, collaborations and in-licences involve numerous risks, including, but not limited to substantial cash expenditures, technology development risks, potentially dilutive issuances of equity securities, incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition, difficulties in assimilating the operations of the acquired companies, entering markets in which the Company has limited or no direct experience, and potential loss of the Company's key employees or key employees of the acquired companies or businesses.

The Company has experience in making acquisitions, entering collaborations and in-licensing prescription drug product candidates; however, the Company cannot provide assurance that any acquisition, collaboration or in-licence will result in short-term or long-term benefits to it. The Company may incorrectly judge the value or worth of an acquired company or business or in-licensed prescription drug product candidate. In addition, the Company's future success would depend in part on its ability to manage the rapid growth associated with some of these acquisitions, collaborations and in-licences. The Company cannot provide assurance that it would be able to successfully combine its business with that of acquired businesses, manage a collaboration or integrate in-licensed prescription drug product candidates. Furthermore, the development or expansion of the Company's business may require a substantial capital investment by the Company.

### ***Negative Results of External Clinical Trials or Studies***

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's prescription drug product candidates, or the therapeutic areas in which the Company's prescription drug product candidates compete, could

adversely affect its share price and the Company's ability to finance future development of its prescription drug product candidates, and its business and financial results could be materially and adversely affected.

### ***Product Liability***

The Company currently does not carry any product liability insurance coverage. Even though the Company is not aware of any product liability claims at this time, its business exposes itself to potential product liability, recalls and other liability risks that are inherent in the sale of consumer products. The Company can provide no assurance that such potential claims will not be asserted against it. A successful liability claim or series of claims brought against the Company could have a material adverse effect on its business, financial condition and results of operations.

Although the Company intends to obtain adequate product liability insurance, it cannot provide any assurances that it will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability cover that may be obtained by the Company could have a material adverse effect on its business, financial condition and results of operations.

Some of the Company's agreements with third parties might require it to maintain product liability insurance. If the Company cannot obtain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on its operations.

### ***Enforcing Contracts***

Due to the nature of the business of the Company and the fact that certain of its contracts involve psilocybin, the use of which is not legal under Canadian or U.S. federal law and in certain other jurisdictions, the Company may face difficulties in enforcing its contracts in Canadian or U.S. federal and state courts. The inability to enforce any of its contracts could have a material adverse effect on its business, operating results, financial condition or prospects.

In order to manage its contracts with contractors, the Company will ensure that such contractors are appropriately licensed. Were such contractors to operate outside the terms of these licences, the Company may experience an adverse effect on its business, including the pace of development of its product.

### ***Product Recalls***

Manufacturers, producers and distributors of products are sometimes subject to the recall or return of their products for a variety of reasons, including product defects, such as contamination, unintended harmful side effects or interactions with other substances, packaging safety and inadequate or inaccurate labelling disclosure. If any of the Company's products are recalled due to an alleged product defect or for any other reason, the Company could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Company may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may require significant management attention.

Although the Company's suppliers have detailed procedures in place for testing its products, there can be no assurance that any quality, potency or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action or lawsuits. Additionally, if the Company is subject to recall, the image of the Company could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for the Company's products and could have a material adverse effect on the results of operations and financial condition of the Company. Additionally, product recalls may lead to increased scrutiny of the Company's operations by regulatory agencies, requiring further management attention, potential loss of applicable licences and potential legal fees and other expenses.

### ***Distribution and Supply Chain Interruption***

The Company is susceptible to risks relating to distributor and supply chain interruptions. Distribution in Canada and other jurisdictions will be largely accomplished through independent contractors, therefore, an interruption (e.g., a labour strike) for any length of time affecting such independent contractors may have a significant impact on the Company's ability to sell its products. Supply chain interruptions, including a production or inventory disruption,

could impact product quality and availability. Inherent to producing products is a potential for shortages or surpluses in future years if demand and supply are materially different from long-term forecasts. The Company monitors category trends and regularly reviews maturing inventory levels.

### ***Difficulty to Forecast***

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the psychedelic pharmaceutical industry. A failure in the demand for the Company's psychedelic pharmaceutical industry products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

### ***Promoting the Brand***

Promoting the Company's brand will be critical to creating and expanding a customer base. Promoting the brand will depend largely on the Company's ability to provide psychedelic pharmaceutical products to the market. Further, the Company may, in the future, introduce new products or services that its customers do not like, which may negatively affect the brand and reputation. If the Company fails to successfully promote its brand or if it incurs excessive expenses in this effort, its business and financial results from operations could be materially adversely affected.

If there are changes in the applicable regulatory framework governing the promotion, branding and marketing of the Company's products, the Company's ability to promote and 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.

### ***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. Further, the Company's business involves the growing of an agricultural product and is subject to the risks inherent in the agricultural business, such as insects, plant diseases and similar agricultural risks.

### ***Success of Quality Control Systems***

The quality and safety of the Company's products are critical to the success of its business and operations. As such, it is imperative that the Company (and its service providers') quality control systems operate effectively and successfully. Quality control systems can be negatively impacted by the design of the quality control systems, the quality of training programs and adherence by employees to quality control guidelines. Any significant failure or deterioration of such quality control systems could have a material adverse effect on the Company's business and operating results.

### ***Reliance on Key Inputs***

The Company's business is expected to be dependent on a number of key inputs and their related costs including raw materials and supplies. Any significant interruption or negative change in the availability or economics of the supply chain for key inputs could materially impact the business, financial condition and operating results of the Company. Examples of potential risks include, but are not limited to, the risk that crops may become diseased or victim to insects or other pests and contamination, or subject to extreme weather conditions such as excess rainfall, freezing temperature, or drought, all of which could result in low crop yields, decreased availability of mushrooms, and higher acquisition prices. Any inability to secure required supplies and services or to do so on appropriate terms could have a materially adverse impact on the business, financial condition and operating results of the Company.

### ***Liability Arising from Fraudulent or Illegal Activity***

The Company is exposed to the risk that its employees, independent contractors, consultants, service providers and licensors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional undertakings of unauthorized activities, or reckless or negligent undertakings of authorized activities, in each case on the Company's behalf or in its service that violate (i) various laws and regulations, including healthcare laws and regulations, (ii) laws that require the true, complete and accurate reporting of financial information or data, (iii) the terms of the Company's agreements with third parties. Such misconduct could expose the Company to, among other things, class actions and other litigation, increased regulatory inspections and related sanctions, and lost sales and revenue or reputational damage.

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. Such misconduct may result in legal action, significant fines or other sanctions and could result in loss of any regulatory licence held by the Company at such time. The Company may be subject to security breaches at its facilities or in respect of electronic document or data storage, which could lead to breaches of applicable privacy laws and associated sanctions or civil or criminal penalties; events, including those beyond the control of the Company, may damage its operations. In addition, these events may negatively affect customers' demand for the Company's products. Such events include, but are not limited to, non-performance by third party contractors; increases in materials or labour costs; breakdown or failure of equipment; failure of quality control processes; contractor or operator errors; and major incidents and/or catastrophic events such as fires, explosions, earthquakes or storms. As a result, there is a risk that the Company may not have the capacity to meet customer demand or to meet future demand when it arises. Failure to comply with health and safety laws and regulations may result in additional costs for corrective measures, penalties or in restrictions on the Company's manufacturing operations.

### ***Operating Risk and Insurance Coverage***

The Company has directors and officers insurance to protect its assets, operations and employees. The Company's insurance is subject to coverage limits and exclusions and may not be available for the risks and hazards to which the Company is expected to be exposed. In addition, no assurance can be given that such insurance will be adequate to cover the Company's liabilities or will be generally available in the future, or if available, that premiums will be commercially justifiable. If the Company were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if the Company were to incur such liability at a time when it is not able to obtain liability insurance, its business, results of operations and financial condition could be materially adversely affected.

### ***Costs of Operating as Public Company***

As a public company the Company will incur significant legal, accounting and other expenses. As a public company, the Company is subject to various securities rules and regulations, which impose various requirements on the Company, including the requirement to establish and maintain effective disclosure and financial controls and corporate governance practices. The Company's management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and make some activities more time-consuming and costly.

### ***Management of Growth***

The Company may be subject to growth-related risks, including capacity constraints and pressure on its internal systems and controls. The ability of the Company to manage growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. The inability of the Company to deal with this growth may have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

## ***Conflicts of Interest***

The Company may be subject to various potential conflicts of interest because of the fact that some of its officers and directors may be engaged in a range of business activities. The 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 outside business interests could require significant time and attention of the Company's executive officers and directors.

In addition, the Company may also 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, and 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, in the event that 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 Board is required to act honestly, in good faith and in the best interests of the Company.

## ***Foreign Operations***

In addition to operations carried out in Canada, the Company intends to carry out international operations through an office in Ireland. As a result, the Company may be subject to political, economic and other uncertainties, including, but not limited to, cancellation or modification of contract rights, foreign exchange restrictions, currency fluctuations, export quotas, royalty and tax increases and other risks arising out of foreign governmental sovereignty over the areas in which the Company's operations are conducted, as well as risks of loss due to civil strife, acts of war, guerrilla activities and insurrections.

The Company's international operations may also be adversely affected by laws and policies of Canada affecting foreign trade, taxation and investment. In the event of a dispute arising in connection with its foreign operations, the Company may be subject to the exclusive jurisdiction of foreign courts or may not be successful in subjecting foreign persons to the jurisdiction of courts in Canada or enforcing Canadian judgments in foreign jurisdictions.

Similarly, to the extent that the Company's assets are located outside of Canada, investors may have difficulty collecting from the Company any judgments obtained in the Canadian courts and predicated on the civil liability provisions of securities laws. Consequently, investors may be effectively prevented from pursuing remedies against the Company under Canadian securities laws or otherwise. The Company may also be hindered or prevented from enforcing its rights with respect to a governmental entity or instrumentality because of the doctrine of sovereign immunity.

## ***Cybersecurity and Privacy Risk***

The Company's information systems and any third-party service providers and vendors are vulnerable to an increasing threat of continually evolving cybersecurity risks. These risks may take the form of malware, computer viruses, cyber threats, extortion, employee error, malfeasance, system errors or other types of risks, and may occur from inside or outside of the respective organizations. Cybersecurity risk is increasingly difficult to identify and quantify and cannot be fully mitigated because of the rapid evolving nature of the threats, targets and consequences. Additionally, unauthorized parties may attempt to gain access to these systems through fraud or other means of deceiving third-party service providers, employees or vendors. The Company's operations depend, in part, on how well networks, equipment, IT systems and software are protected against damage from a number of threats. These operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. However, if the Company is unable or delayed in maintaining, upgrading or replacing IT systems and software, the risk of a cybersecurity incident could materially increase. Any of these and other events could result in information system failures, delays and/or increases in capital

expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Company's reputation and results of operations.

The Company may collect and store certain personal information about customers and are responsible for protecting such information from privacy breaches. A privacy breach may occur through procedural or process failure, information technology malfunction, or deliberate unauthorized intrusions. In addition, theft of data is an ongoing risk whether perpetrated via employee collusion or negligence or through deliberate cyber-attack. Any such privacy breach or theft could have a material adverse effect on the Company's business, financial condition and results of operations.

In addition, there are a number of laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the privacy rules under the *Personal Information Protection and Electronics Documents Act* (Canada) ("PIPEDA") and where applicable, provincial legislation governing personal health information, protect medical records and other personal health information by limited their use and disclosure of health information to the minimum level reasonably necessary to accomplish the intended purpose. If the Company were found to be in violation of the privacy or security rules under PIPEDA or other laws protecting the confidentiality of medical patients health information, the Company could be subject to sanctions and civil or criminal penalties, which could increase its liabilities, harm its reputation and have a material adverse effect on the Company's business, financial condition and results of operations.

### ***Environmental Regulation and Risks***

The Company's operations are subject to environmental regulations that mandate, among other things, the maintenance of air and water quality standards and land reclamation. They also set forth limitations on the generation, transportation, storage and disposal of solid and hazardous waste. Environmental legislation is evolving in a manner which could stricter standards and enforcement, increased fines and penalties for non-compliance, more stringent environmental assessments of proposed projects and a heightened degree of responsibility for companies and their officers, directors and employees. There is no assurance that future changes in environmental regulation, if any, will not adversely affect the Company's operations.

Failure to comply with applicable laws, regulations and permitting requirements may result in enforcement actions thereunder, including orders issued by regulatory or judicial authorities causing operations to cease or be curtailed, and may include corrective measures requiring capital expenditures, installation of additional equipment, or remedial actions. The Company may be required to compensate those suffering loss or damage by reason of its operations and may have civil or criminal fines or penalties imposed for violations of applicable laws or regulations.

Amendments to current laws, regulations and permits governing psychedelics and related products, or more stringent implementation thereof, could have a material adverse impact on the Company and cause increases in expenses, capital expenditures or production costs or reduction in levels of production or require abandonment or delays in development.

### ***Decriminalisation of Psychedelics***

Despite the current status of many psychotropic substances as a Schedule II and Schedule I controlled substances in the United States and Canada, respectively, there may be changes in the status of some of these substances under the laws of certain jurisdictions. Possession of psilocybin, for example, was voted to be decriminalised in May 2019 in Denver and in November 2020, voters in Oregon approved the legal medical use of "psilocybin products," including magic mushrooms, to treat mental health conditions in licensed facilities with registered therapists (Measure 109). The legalization of psychedelics with inadequate regulatory oversight may lead to the development of psychotropic tourism in such states in clinics without proper therapeutic infrastructure or adequate clinical research. The expansion of such an industry which could put patients at risk may bring reputational and regulatory risk to the entire industry, leading to challenges for the Company to achieve regulatory approval. The legalization of psilocybin, and potentially other psychotropic compounds in the future may also impact commercial sales for the Company due to a reduced barrier to entry leading to a risk of increasing competition.



### ***Forward-looking statements may prove to be inaccurate***

Investors should not place undue reliance on forward-looking statements. By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties, of both general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate.

### ***Effects of Inflation***

Global markets have recently experienced increased rates of inflation. Inflation itself, as well as certain governmental efforts to combat inflation, may have significant negative effects on any economy which the Company does business. Past governmental efforts to curb inflation have involved certain drastic economic measures, which had a materially adverse impact on the level of economic activity in these countries. Any future economic measures to curb inflation could be expected to have similar adverse effects on the level of economic activity in the market which the Company does business and, in turn, on the operations of the Company.

### ***Political and Economic Conditions***

Political and economic conditions directly affect the Company's business and can result in a material adverse effect on the Company. Macroeconomic policies imposed by foreign governments could have significant impact on the Company. As certain global markets experience increased inflation, certain government actions to control inflation may have significant impact on the Company.

The Company cannot control or predict foreign government implementation of changes to existing policies that may impact the Company's operations in foreign markets and, consequently, its business. The Company's business, operating results and financial condition and prospects, as well as the market price of its securities, may be adversely affected by changes in government public policies, whether federal, state or local, that affect, without limitation:

- inflation;
- fluctuations in exchange rates;
- exchange controls and restrictions on remittances abroad;
- interest rates and monetary policies;
- import and export controls;
- liquidity of domestic capital, credit and financial markets;
- expansion or contraction of foreign economies, as measured by rates of growth in gross domestic product;
- fiscal policies; and
- other political, social and economic developments in or affecting foreign markets.

Government policies and measures to combat inflation, along with public speculation about such policies and measures, have often had adverse effects on global economies, have contributed to economic uncertainty and may increase volatility in foreign securities markets. Government action to control inflation may involve actions such as price and salary controls, currency devaluations, capital limitations, limits on imports and other actions which could significantly impact the operations of the Company.

Other policies and measures adopted by governments, include interest rate adjustments, intervention in the currency markets or actions to adjust or fix the value of the local currency may adversely affect the target market's economy, the Company's business and results of operations.

Uncertainty over whether federal governments will implement reforms or changes in policy or regulation affecting these or other factors in the future may affect economic performance and contribute to economic uncertainty in markets that the Company operates or relies on, which may in turn have adverse effects on the Company's operations in the market and consequently on the results of its operations.

### ***Application and Interpretation of Tax Laws***

The Company is subject to direct and indirect taxes in various foreign jurisdictions. The amount of tax that the Company pays, directly or indirectly, is subject to the interpretation of applicable tax laws in the jurisdictions of

operations in which the Company has interests. The Company has taken and will continue to take tax positions based on the application and interpretation of tax laws, but tax accounting often involves complex matters and judgment is required in determining the Company's foreign provisions for taxes and other tax liabilities. There can be no assurance that a taxing authority will not have a different interpretation of the law and assess the Company, or the operations in which the Company has interests, with additional taxes. Further, the Company's future effective tax rates could be impacted by changes in tax laws or regulations, and changing interpretation of existing laws or regulations. Both domestic and international tax laws, and interpretation of the tax laws, are subject to change as a result of changes in fiscal policy, changes in legislation, evolution of regulation and court rulings. The application of these tax laws and related regulations is subject to legal and factual interpretation, judgment and uncertainty.

### ***Enforcement of Civil Liabilities***

Certain of the Company's subsidiaries and assets are located outside of Canada. Accordingly, it may be difficult for investors to enforce within Canada any judgments obtained against the Company, including judgments predicated upon the civil liability provisions of applicable Canadian securities laws or otherwise. Consequently, investors may be effectively prevented from pursuing remedies against the Company under Canadian securities laws or otherwise.

The Company has subsidiaries incorporated in the United States and Ireland. It may not be possible for shareholders to effect service of process outside of Canada against the directors and officers of the Company who are not resident in Canada. In the event a judgment is obtained in a Canadian court against one or more of such persons for violations of Canadian securities laws or otherwise, it may not be possible to enforce such judgment against persons not resident in Canada. Additionally, it may be difficult for an investor, or any other person or entity, to assert Canadian securities law or other claims in original actions instituted in the United States and Ireland. Courts in such jurisdictions may refuse to hear a claim based on a violation of Canadian securities laws or otherwise on the grounds that such jurisdiction is not the most appropriate forum to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the local law, and not Canadian law, is applicable to the claim. If Canadian law is found to be applicable, the content of applicable Canadian law must be proven as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by foreign law.

### **Risks Related to Intellectual Property**

#### ***Trademark Protection***

Failure to register trademarks for the Company or its products could require the Company to rebrand its products resulting in a material adverse impact on its business.

#### ***Trade Secrets***

The Company relies on third parties to develop its products and, as a result, must share trade secrets with them. The Company seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of the Company's collaborators, advisors, employees and consultants to publish data potentially relating to its trade secrets. Its academic and clinical collaborators typically have rights to publish data, provided that the Company is notified in advance and may delay publication for a specified time in order to secure any intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by the Company, although in some cases the Company may share these rights with other parties. The Company may also conduct joint research and development programs which may require it to share trade secrets under the terms of research and development collaboration or similar agreements. Despite the Company's efforts to protect its trade secrets, the Company's competitors may discover its trade secrets, either through breach of these agreements, independent development or publication of information. A competitor's discovery of the Company's trade secrets may impair its competitive position and could have a material adverse effect on its business and financial condition.

#### ***Patent Law Reform***

As is the case with other biotechnology and pharmaceutical companies, the Company's success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry

is a technologically and legally complex process, and obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of the Company's and its licensors' or collaborators' patent applications and the enforcement or defense of the Company or its licensors' or collaborators' issued patents.

### ***Patent Litigation and Intellectual Property***

The Company has filed a number of provisional patent applications but even if regular patent applications are filed claiming priority to one or more of the provisional patent applications, there can be no assurance that any or all of these patent applications will issue into a valid patent. Such failure to issue could have a material adverse effect on the Company. In the event that a patent issued to the Company is challenged, any of the Company's patents may be invalidated. The Company could also become involved in interference or impeachment proceedings in connection with one or more of its patents or patent applications to determine priority of invention.

Patent litigation is widespread in the pharmaceutical industry and the Company cannot predict how this will affect its efforts to form strategic alliances, conduct clinical testing, or manufacture and market any of its prescription drug product candidates that it may successfully develop. If the Company becomes involved in any litigation, interference, impeachment or other administrative proceedings, it will likely incur substantial expenses and the efforts of its technical and management personnel will be significantly diverted. The Company cannot make any assurances that it will have the financial or other resources necessary to enforce or defend a patent infringement or proprietary rights violation action. Moreover, if the Company's products infringe patents, trademarks or proprietary rights of others, it could, in certain circumstances, become liable for substantial damages, which also could have a material adverse effect on the business of the Company, its financial condition and results of operation. Patent litigation is less likely during development as many jurisdictions contain exemptions from patent infringement for the purpose of obtaining regulatory approval of a product. Where there is any sharing of patent rights either through co-ownership or different licensed "fields of use", one owner's actions could lead to the invalidity of the entire patent. If the Company is unable to avoid infringing the patent rights of others, the Company may be required to seek a licence, defend an infringement action or challenge the validity of the patents in court. Such results could have a material adverse effect on the Company. Regardless of the outcome, patent litigation is costly and time consuming. In some cases, the Company may not have sufficient resources to bring these actions to a successful conclusion, and, even if the Company is successful in these proceedings, it may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on the Company.

Any infringement or misappropriation of the Company's intellectual property could damage its value and limit its ability to compete. In addition, the Company's ability to enforce and protect its intellectual property rights may be limited in certain countries outside the U.S., which could make it easier for competitors to capture market position in such countries by utilizing technologies that are similar to those developed or licensed by the Company. Competitors may also harm the Company's sales by designing products that mirror the capabilities of its products or technology without infringing on its intellectual property rights. If the Company does not obtain sufficient protection for its intellectual property, or if it is unable to effectively enforce its intellectual property rights, its competitiveness could be impaired, which would limit its growth and future revenue. The Company may also find it necessary to bring infringement or other actions against third parties to seek to protect its intellectual property rights. Litigation of this nature, even if successful, is often expensive and time-consuming to prosecute and there can be no assurance that the Company will have the financial or other resources to enforce its rights or be able to enforce its rights or prevent other parties from developing similar technology or designing around its intellectual property.

The Company is not aware of any infringement by it of any person's or entity's intellectual property rights. In the event that products sold by the Company are deemed to infringe upon the patents or proprietary rights of others, the Company could be required to modify its products or obtain a licence for the manufacture and/or sale of such products or cease selling such products. In such event, there can be no assurance that the Company would be able to do so in a timely manner, upon acceptable terms and conditions, or at all, and the failure to do any of the foregoing could have a material adverse effect upon the Company's business. If the Company's products or proposed products are deemed to infringe or likely to infringe upon the patents or proprietary rights of others, the Company could be subject to injunctive relief and, under certain circumstances, become liable for damages, which could also have a material adverse effect on the Company's business and its financial condition.

## ***Protection of Intellectual Property***

The Company will be able to protect its intellectual property from unauthorized use by third parties only to the extent that the Company's proprietary technologies, key products and any future products are covered by valid and enforceable intellectual property rights including patents or are effectively maintained as trade secrets and provided the Company has the funds to enforce its rights, if necessary.

## ***Third-Party Licences***

A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third-party patent rights cover the Company's products or services, the Company or its strategic collaborators would be required to seek licences from the holders of these patents in order to manufacture, use or sell these products and services and payments under them would reduce the Company's profits from these products and services. The Company is currently unable to predict the extent to which it may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights and whether a licence to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents issued in the future that are unavailable to licence on acceptable terms. The Company's inability to obtain such licences may hinder or eliminate its ability to manufacture and market its products.

Further, if the Company obtains third-party licences but fails to pay annual maintenance fees, development and sales milestones, or it is determined that the Company does not use commercially reasonable efforts to commercialize licensed products, the Company could lose its licences which could have a material adverse effect on its business and financial condition.

## **Financial and Accounting Risks**

### ***Substantial Number of Authorized but Unissued Common Shares***

The Company has an unlimited number of Common Shares that may be issued by the Company board without further action or approval of the Shareholders. While the Company board will be required to fulfill its fiduciary obligations in connection with the issuance of such Common Shares, the Common Shares may be issued in transactions with which not all of the shareholders of the Company agree, and the issuance of such Common Shares will cause dilution to the ownership interests of the shareholders of the Company.

### ***Dilution***

The Company may issue additional Common Shares in subsequent offerings (including through the sale of securities convertible into or exchangeable for Common Shares) and on the exercise of stock options or other securities exercisable for Common Shares. The Company cannot predict the size of future issuances of Common Shares or the effect that future issuances and sales of Common Shares will have on the market price of the Common Shares. Issuances of a substantial number of additional Common Shares, or the perception that such issuances could occur, may adversely affect prevailing market prices for the Common Shares. With any additional issuance of Common Shares, investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

### ***Negative Cash Flow from Operating Activities and Going Concern***

The Company has had negative cash flow from operating activities since inception. Drug development involves long lead times, is very expensive and involves many variables of uncertainty. As such, significant capital investment will be required to achieve the Company's existing plans. The Company's net losses have had and will continue to have an adverse effect on, among other things, shareholder equity, total assets and working capital. The Company expects that losses may fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial based on the stage of development of its principal programs. The Company cannot predict when it will become profitable, if at all. Accordingly, the Company may be required to obtain additional financing in order to meet its future cash commitments.

The threat of the Company's ability to continue as a going concern will be removed only when, in the opinion of the Company's auditor, the Company's revenues have reached a level that is able to sustain its business operations. If the

Company is unable to obtain additional financing from outside sources and eventually generate enough revenues, the Company may be forced to sell a portion or all of the Company's assets, or curtail or discontinue the Company's operations. If any of these events happen, shareholders could lose all or part of their investment. The Financial Statements do not include any adjustments to the Company's recorded assets or liabilities that might be necessary if the Company becomes unable to continue as a going concern.

### ***Additional Capital Requirements***

As a research and development company, the Company expects to spend substantial funds to continue the research, development and testing of its prescription drug product candidates and to prepare to commercialize products subject to applicable regulatory approval. Substantial additional financing may be required if the Company is to be successful in continuing to develop its business and its products. No assurances can be given that the Company will be able to raise the additional capital that it may require for its anticipated future development. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities. There is no assurance that additional financing will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations or anticipated expansion. The Company's ability to successfully raise additional capital and maintain liquidity may be impaired by factors outside of its control, such as a shift in consumer attitudes towards certain therapeutic methods or a downturn in the economy.

### ***Lack of Significant Product Revenue***

To date, the Company has generated little product revenue and cannot predict when and if it will generate significant product revenue. The Company's ability to generate significant product revenue and ultimately become profitable depends upon its ability, alone or with partners, to successfully develop its prescription drug product candidates, obtain regulatory approval and commercialize products, including any of its current prescription drug product candidates or other prescription drug product candidates that it may develop, in-license or acquire in the future. The Company does not anticipate generating revenue from the sale of products for the foreseeable future. The Company expects its research and development expenses to increase in connection with its ongoing activities, particularly as it advances its prescription drug product candidates through clinical trials.

### ***Estimates or Judgments Relating to Critical Accounting Policies***

The preparation of Financial Statements in conformity with the International Financial Reporting Standards requires management to make estimates and assumptions that affect the amounts reported in the Financial Statements and accompanying notes. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, as provided in the notes to the Financial Statements, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. The Company's operating results may be adversely affected if the assumptions change or if actual circumstances differ from those in the assumptions, which could cause its operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the share price of the Company. Significant assumptions and estimates used in preparing the Financial Statements include those related to income tax credits receivable, share based payments, impairment of non-financial assets, fair value of biological assets, as well as cost recognition.

### ***Inadequate Internal Controls***

If the Company fails to maintain an effective system of internal controls, the Company might not be able to report its financial results accurately or prevent misstatement; and in that case, the Company's shareholders could lose confidence in its financial reporting, which would harm its business and could negatively impact the value of its shares. While the Company believes that it has sufficient personnel and review procedures to allow it to maintain an effective system of internal controls, there can be no assurance that the Company will always successfully detect misstatements or implement necessary improvements in a timely fashion.

## **Risks Related to the Common Shares**

### ***Market for the Common Shares***

There can be no assurance that an active trading market for the Common Shares will develop or, if developed, that any market will be sustained. The Company cannot predict the prices at which the Common Shares will trade. Fluctuations in the market price of the Common Shares could cause an investor to lose all or part of its investment in Common Shares. Factors that could cause fluctuations in the trading price of the Common Shares include: (i) announcements of new offerings, products, services or technologies; commercial relationships, acquisitions or other events by the Company or its competitors; (ii) price and volume fluctuations in the overall stock market from time to time; (iii) significant volatility in the market price and trading volume of companies commercializing psychedelic pharmaceuticals; (iv) fluctuations in the trading volume of the Common Shares or the size of the Company's public float; (v) actual or anticipated changes or fluctuations in the Company's results of operations; (vi) whether the Company's results of operations meet the expectations of securities analysts or investors; (vii) actual or anticipated changes in the expectations of investors or securities analysts; (viii) litigation involving the Company, its industry, or both; (ix) regulatory developments; (x) general economic conditions and trends; (xi) major catastrophic events; (xii) escrow releases, sales of large blocks of the Common Shares; (xiii) departures of key employees or members of management; or (xiv) an adverse impact on the Company from any of the other risks cited herein.

### ***Significant Sales of the Common Shares***

Although Common Shares held by existing shareholders of the Company will be freely tradable under applicable securities legislation, the Common Shares held by the Company's directors, executive officers, Control persons and certain other securityholders may be subject to contractual lock-up restrictions and may also be subject to escrow restrictions pursuant to the policies of the Exchange. Sales of a substantial number of the Common Shares in the public market after the expiry of lock-up or escrow restrictions, or the perception that these sales could occur, could adversely affect the market price of the Common Shares and may make it more difficult for investors to sell Common Shares at a favourable time and price.

### ***Volatile Market Price for the Common Shares***

The securities market in Canada has recently experienced a high level of price and volume volatility, and the market prices of securities of many companies have experienced wide fluctuations in price which have not necessarily been related to the operating performance, underlying asset values or prospects of such companies. There can be no assurance that continual fluctuations in price will not occur. It may be anticipated that any market for the Common Shares will be subject to market trends generally, notwithstanding any potential success of the Company. The value of the Common Shares distributed hereunder will be affected by such volatility.

The volatility of the Common Shares may affect the ability of holders to sell the Common Shares at an advantageous price or at all. Market price fluctuations in the Common Shares may be adversely affected by a variety of factors relating to the Company's business, including fluctuations in the Company's operating and financial results, such results failing to meet the expectations of securities analysts or investors and downward revisions in securities analysis' estimates in connection therewith, sales of additional Common Shares, governmental regulatory action, adverse change in general market conditions or economic trends, acquisitions, dispositions or other material public announcements by the Company or its competitors, along with a variety of additional factors, including, without limitation, those set forth under the heading "Cautionary Note Regarding Forward-Looking Information". In addition, the market price for securities on stock markets, including the Exchange is subject to significant price and trading fluctuations. These fluctuations have resulted in volatility in the market prices of securities that often has been unrelated or disproportionate to changes in operating performance. These broad market fluctuations may materially adversely affect the market price of the Company.

Additionally, the value of the Common Shares is subject to market value fluctuations based upon factors that influence the Company's operations, such as legislative or regulatory developments, competition, technological change and changes in interest rates or foreign exchange rates. There can be no assurance that the market price of the Common Shares will not experience significant fluctuations in the future, including fluctuations that are unrelated to the Company's performance.

### ***Tax Issues***

There may be income tax consequences in relation to the Common Shares, which will vary according to circumstances. Independent advice from tax and legal advisers should be obtained.

### ***No Dividends***

The Company's current policy is, and will be, to retain earnings to finance the development and enhancement of its products and to otherwise reinvest in the Company. Therefore, the Company does not anticipate paying cash dividends on the Common Shares in the foreseeable future. The Company's dividend policy will be reviewed from time to time by the Board in the context of its earnings, financial condition and other relevant factors. Until the time that the Company does pay dividends, which it might never do, its shareholders will not be able to receive a return on their Common Shares unless they sell them.

### ***Additional information***

Additional information on the Company has been filed electronically through SEDAR and is available online at [www.sedar.com](http://www.sedar.com).

### ***Approval***

The Board has approved the disclosure in this MD&A.