# ENTHEON BIOMEDICAL CORP.

## MANAGEMENT DISCUSSION AND ANALYSIS

Fiscal year ended November 30, 2021

Fiscal year ended November 30, 2021

#### OVERVIEW

The following management discussion and analysis ("**MD&A**") of the financial position of Entheon Biomedical Corp. ("**Entheon**" or the "**Company**"), and results of operations prepared as of March 28, 2022, should be read in conjunction with the audited consolidated financial statements for the fiscal year ended November 30, 2021. All amounts are stated in Canadian dollars unless otherwise indicated. These audited consolidated financial statements together with this MD&A are intended to provide investors with a reasonable basis for assessing the financial performance of the Company.

Entheon is a biotechnology research and development company incorporated under the Canadian Business Corporations Act (the "**CBCA**"). Entheon is the result of a three-cornered amalgamation, completed on November 5, 2020. See below under the heading "*Corporate Structure*". All capitalized terms not defined herein have the meanings assigned to them in the listing statement of the Company dated November 12, 2020 (the "**Listing Statement**").

Additional information relating to the Company, including the Listing Statement and the Company's most recent Annual Information Form, is available under the Company's profile on SEDAR at <u>www.sedar.com</u>.

#### FORWARD LOOKING STATEMENTS

The information provided in this report contains forward-looking statements within the meaning of applicable Canadian securities legislation, including, without limitation, statements concerning future events or future performance with respect to the Company's project; business approach and plans, and business transactions including new business partnerships and consultancy engagements and the expected benefits therefrom. Statements in this report that are not historical facts are forward-looking statements involving known and unknown risks and uncertainties, which could cause actual results to vary considerably from these statements. Readers are cautioned not to put undue reliance on forward-looking statements. In some cases, forward-looking statements are preceded by, followed by or include words such as "may", "will", "would", "could", "should", "believes", "estimates", "projects", "goal", or the negative of those words or other similar or comparable words.

In making the forward-looking statements in this MD&A, the Company has applied several material assumptions including, but not limited to, the assumption that: whether the Company will continue to be in compliance with regulatory requirements; possible events, conditions or financial performance that is based on assumptions about future economic conditions and courses of action; general economic, financial market, regulatory and political conditions in which the Company operates; the effect of the COVID-19 pandemic on the personnel, and business operations and financial condition of the Company and its business partners.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Entheon to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements including, without limitation: the Company's history of net losses and negative cash flows from operations and expectation of future losses and negative cash flows from operations; risks related to the ability to obtain financing needed to fund the continued development of the Company's business; risks related to the Company's failure to retain key personnel and hire additional personnel needed to

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develop its business; the Company's ability to manage anticipated and unanticipated costs; impact of COVID-19; and general risks and uncertainties related to the Company's prospects and business strategy, as well as those factors discussed in the section entitled "*Risk Factors*."

Although management of Entheon believes that the assumptions made and the expectations represented by such statements are reasonable, there can be no assurance that a forward-looking statement herein will prove to be accurate. In addition, although the Company has attempted to identify important factors that could cause actual achievements, events or conditions to differ materially from those identified in the forward-looking statements, there may be other factors that cause achievements, events or conditions not to be as anticipated, estimated or intended. Many of the foregoing factors are beyond the Company's ability to control or predict. These forward-looking statements are based on the beliefs, expectations and opinions of management on the date the statements are made and the Company does not assume any obligation to update forward-looking statements, except as required by applicable securities laws, if circumstances or management's beliefs, expectations or opinions should change. For the reasons set forth above, forward-looking statements are inherently unreliable, and investors should not place undue reliance on forward-looking statements.

#### CORPORATE STRUCTURE

#### Name, Address and Incorporation

The Company was incorporated on April 6, 2010, pursuant to the CBCA under the name "M.P.V. Explorations Inc./Explorations M.P.V. Inc." On October 23, 2018, the Company changed its name to "MPV Exploration Inc." The head office of the Company is located at Suite 720 – 999 West Broadway Vancouver, British Columbia, V5Z 1K5 and the registered office is located at 10th Floor, 595 Howe Street, Vancouver, British Columbia V6C 2T5.

On November 5, 2020, the Company completed a Fundamental Change as defined by the policies of the CSE whereby the former entity known as Entheon Biomedical Corp. ("Former Entheon") completed a reverse takeover of the Company by way of a three-cornered amalgamation (the "RTO") all pursuant to an amalgamation agreement between the Company, Former Entheon and 1254912 B.C. Ltd., which was previously a wholly-owned subsidiary of the Company ("MPV Sub"). Immediately prior to the completion of the RTO, the Company completed a consolidation of its common shares ("Common Shares") (the "Consolidation") on the basis of one post-Consolidation common share for every three pre-Consolidation common shares held by a shareholder of the Company prior to completion of the RTO. Pursuant to the RTO, among other things: (i) Former Entheon amalgamated with MPV Sub under subsection 269 of the Business Corporations Act (British Columbia)to form Entheon Holdings Corp. ("Entheon Holdings"); (ii) shareholders of Entheon Holdings received one post-Consolidation Common Share in exchange for each common share of Entheon Holdings held by such shareholder immediately prior to the effective time of the RTO; and (iii) MPV changed its name to "Entheon Biomedical Corp." and Entheon Holdings became a wholly-owned subsidiary of the Company. After completion of the RTO, the Company took over the business of Entheon Holdings and although the RTO resulted in Entheon Holdings becoming a wholly-owned subsidiary of the Company. the RTO constituted a reverse take-over of the Company because former shareholders of Entheon Holdings held approximately 73.90% of the issued and outstanding common shares of the Company immediately after completion of the RTO. On November 12, 2020, the Common Shares began trading on the CSE under the symbol "ENBI," on November 26, 2020 the Common Shares began trading on

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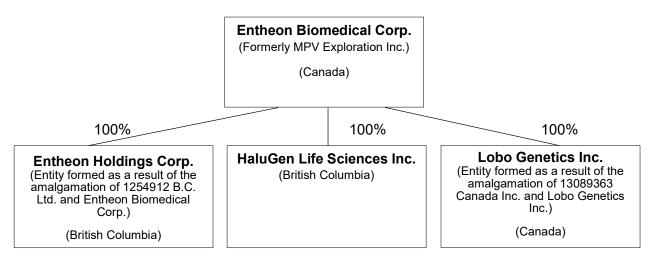
the Frankfurt Stock Exchange under the symbol "1XU1," and on May 5, 2021 the Common Shares began trading on the OTCQB Venture Market under the symbol "ENTBF."

#### Change in year-end

Effective November 5, 2020, the Company changed its financial year-end from March 31 to November 30 in connection with the RTO. The change in year-ended resulted in the Company filing a one time, 7-month transition year for the period of April 1, 2020 to November 30, 2020. Subsequent to the transition year, the Company's financial year became and currently is from the period of December 1 to November 30. Information regarding the change of year-end can be found in the Amended Notice of Change in Corporate Structure filed on the Company's SEDAR profile at <u>www.sedar.com</u> on November 10, 2020.

#### Intercorporate Relationships

As of the date hereof, the Company has three wholly owned subsidiaries, which are reflected in the organization chart below:



#### **DESCRIPTION OF BUSINESS**

The Company is a biomedical company focused on the research and development of psychedelic drugs and leading-edge biomarkers to provide personalized treatment of addiction disorders, including the development and commercialization of its DMT Products and DMT Delivery System (each defined below). DMT is a chemical substance that naturally occurs in many plants and animals and which is a structural analog of serotonin; it is among the most potent of the classic psychedelic drugs, and is unique in that its effects last only minutes instead of hours. Given the emerging recognition of the therapeutic potential of classic psychedelics for treating mental health disorders and the short acting and powerful nature of DMT, it appears to be an ideal molecular candidate for medical use. Notwithstanding the foregoing, DMT is currently a Schedule III drug under *The Controlled Drugs and Substances Act* (Canada) and a Schedule I drug under *The Controlled Substances Act* (United States) and the *UN Convention 1971* (European Union) and is illegal, under each such legislation, to possess without a prescription or an exemption. As of the date hereof, neither the Health Products and Food

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Branch of Health Canada ("**Health Canada**"), the United States Food and Drug Administration ("**FDA**"), nor the European Medicines Agency ("**EMA**") have approved DMT as a drug for any indication.

#### DMT Products

Entheon seeks to develop and commercialize a portfolio of safe and effective DMT based psychedelic therapeutic products that consist of proprietary DMT drug formulations packaged in single-use containers targeted to treat a number of different addiction and substance use disorders (the "DMT **Products**"). The containers may alternatively take the form of intravenous bags, ampules, or cartridges but in any case will be designed to work within the DMT Delivery System (see below). Each unit of the DMT based drug solution will be offered in tamper-proof packaging and sealed in a way that only allows it to be used for one treatment session. The contents will be a proprietary mixture and will include the exact amount of DMT for the treatment in guestion, along with other non-medicinal ingredients such as stabilizing agents and saline solution. The specific dose of DMT for each type of treatment will be determined from the results of Entheon's clinical trials. It is Entheon's intention that the DMT Products will be used in medical clinics, treatment centres and hospitals to treat patients with addiction and substance use disorders. Essential to the efficacy of each DMT Product to effectively treat the addiction or disorder it is intended to treat are: (i) the amount of DMT contained in each product; and (ii) the particular dosage instructions provided therewith (collectively referred to as the "Dosing Strategies"). To that end, in connection with the development of DMT Products, Entheon is currently developing a number of different proprietary Dosing Strategies to treat different addictions and disorders, each of which will be incorporated into the different DMT Products developed. In the simplest terms, Entheon plans to develop and sell containers of DMT-based medicine containing predetermined amounts of DMT and corresponding instructions to treat patients for specific addictions. The Company is initially focused on treating nicotine addiction.

#### DMT Delivery System

Furthermore, Entheon eventually seeks to develop and commercialize a set of delivery equipment that can effectively pump its DMT Products into patients and thereafter measure their vital signs to ensure the particular DMT Product is working correctly (the "DMT Delivery System" and collectively with the DMT Products, the "DMT Solutions"). The DMT Delivery System will be administered within a proprietary therapeutic protocol, which is intended to integrate intravenous infusion technology with real-time monitoring devices, including electroencephalography ("EEG"). The DMT Delivery System will employ existing target-controlled intravenous pump technology, typically used in analgesia and pain management, to administer the DMT Products according to the Dosing Strategies developed by Entheon. Operating within a calibrated dose range specific to treating addiction, the variable flow rate will gradually bring the patient to a therapeutic level of immersion and maintain a constant subjective experience by integrating real-time neurological signals and other biometric data into the pump flow rate parameters. Unlike other psychedelic experiences, if the patient has an adverse reaction, the DMT Delivery System will allow the experience to be stopped safely and quickly without the need for sedatives or other drug interventions. This DMT Delivery System will also allow for inputs and adjustments by the attending physician, and will include a patient-controlled device to pause or abort the treatment in the rare event of a challenging subjective experience. The DMT Delivery System will include sensors to monitor the patients' brain activity, along with heart rate, body temperature and other vital signs, to ensure that they are responding as expected to the treatment.

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As of the date hereof, Entheon is and has been working with its science advisors and various research organizations to, among other things: (i) develop several Dosing Strategies that will be validated in planned human trials; (ii) design a DMT-focused clinical protocol which integrates the Dosing Strategies within an addiction treatment program to be tested experimentally in clinical trial subjects (the "**DMT Protocol**"); and (iii) complete a number of pre-clinical and clinical studies, the results of which will inform the DMT Protocol. Thereafter, Entheon intends to submit the DMT Protocol and other regulatory documents to Health Canada, the FDA and the EMA for approval. Additionally, as of the date hereof Entheon has conducted research and scientific development relating to its DMT Solutions, the DMT Protocol and design of a DMT-based phase I safety and proof-of-concept clinical study in humans. In addition, Entheon has pursued the prosecution of patents relating to its Dosing Strategies and DMT Protocol. Entheon does not currently generate significant revenue.

Subject to obtaining all requisite regulatory approvals and permits. Entheon intends to generate revenue through the sale of its DMT Products (which will incorporate the Dosing Strategies) and eventually the license of its DMT Delivery System to physicians, clinics and licensed psychiatrists in the United States, certain countries in the European Union and throughout Canada. However, at this time, sales activities have not been planned for specific jurisdictions; these will be developed following receipt of regulatory approvals of the DMT Products and the DMT Protocol, which approvals are subject to a number of uncertainties including, among others, successful completion of the pre-clinical and clinical studies required to be conducted by the Company and those uncertainties described under the heading "Risk Factors – Psychedelic Regulatory Risks and Risks of Violations of Law." Currently, the Company has regulatory approval to conduct the Phase I Study (EBRX-101) at the Centre for Human Drug Research ("CHDR") in the Netherlands pursuant to the CHDR Clinical Study Agreement (discussed in further detail in the Company's Annual Information Form ("AIF") under the heading "Timing and Stage of Research and Development - Developing a Clinical DMT Protocol and Conducting the Phase I Study"). In vivo pre-clinical work was recently completed in Israel pursuant to an agreement with the Company and Science in Action Ltd., an Israeli pre-clinical research company. Further the Company recently completed additional in vitro toxicology assays which were performed in Missouri in the United States by Eurofins Discovery.

#### HaluGen

On January 14, 2021, the Company completed its acquisition of HaluGen Life Sciences Inc. ("**HaluGen**"), its now wholly-owned subsidiary. See disclosure in the Company's AIF, under the heading "*General Development of the Business – Three Year History – Events Subsequent to Fiscal Year Ended November 30, 2020*" and below under the heading "*Acquisition of HaluGen Life Sciences Inc.*" for more information on the acquisition of HaluGen.

HaluGen is a biotech company in the business of developing and commercializing a pre-screening genetic test designed to identify specific DNA biomarkers in order to gauge the risk and potential of adverse reactions toward hallucinogenic drugs (the "**Psychedelics Genetic Test**"). HaluGen has successfully developed a turn-key operation to build, order, ship, process and deliver the Psychedelics Genetic Tests. Customers who purchase the Psychedelics Genetic Test receive a swab kit that is shipped directly to their home and the unique kit identifier is registered on HaluGen's secure online portal existing on the HaluGen Platform (defined below). After a non-invasive cheek swab sample is taken, the kit is returned for laboratory processing at HaluGen's testing facility. A personalized genetic profile with five sensitivity and risk reports for psychedelics is provided to the customer through the HaluGen Platform (as defined below). In addition, customers are provided access to pre-screening

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mental health surveys and relevant peer-reviewed scientific studies. The Psychedelics Genetic Test is the industry's first comprehensive pre-screening genetic test for psychedelics; it analyzes a series of relevant DNA biomarkers along with pre-screening mental health surveys in order to provide insights into an individual's risk and potential of adverse reactions with the use of hallucinogenic drugs. The Psychedelics Genetic Test provides users with personalized reports and actionable insights, delivered directly to one's smartphone or desktop through the HaluGen Platform, providing a convenient and safe means to better understand one's sensitivity to psychedelics. The Psychedelics Genetic Test also provides insights into the short and long-term potential of psychedelic-induced risks, such as psychosis.

In connection with its business, HaluGen has also developed a psychedelics pre-screening mobile and desktop platform (the "HaluGen Platform") that builds upon Lobo's (as defined below) existing genetic testing capabilities for both research and direct to consumer applications. As discussed above, the HaluGen Platform is the mechanism by which HaluGen communicates to its customers, the results, and other information, from a customer's completion of the Psychedelics Genetic Test. The HaluGen Platform provides genetic, personal and familial insights to better inform one's psychedelic assisted therapy experience. By obtaining DNA test results, and data from mental-health surveys, individuals are equipped with valuable insights to make more informed decisions around psychedelic assisted therapy, potential side effects and risk profile.

HaluGen has partnered with companies such as Silo Wellness Inc., 3W Wellness Inc., Maya health PBC, and Psychedelics Today, LLC to help drive brand awareness of the Psychedelics Genetic Test and is currently pursuing additional strategic partnerships with the goal of building distribution and brand awareness.

HaluGen launched direct to consumer sales of the Psychedelics Genetic Test in Canada on April 5, 2021 and in the United states on June 10, 2021. The Psychedelics Genetic Tests retail for CAD\$89 in Canada and USD\$89 in the United States.

#### Lobo

On July 29, 2021, the Company completed its acquisition of Lobo Genetics Inc. ("**Lobo**"), its now wholly-owned subsidiary. See disclosure under the heading "*Acquisition of Lobo Genetics Inc.*" for more information on the acquisition of Lobo.

Lobo is a Toronto-based personalized genetics company with a direct-to-consumer platform (the "Lobo Platform") currently being used in both the psychedelics and cannabis space to provide personalized insights into an individual's response to hallucinogenic and psychoactive drugs. Lobo has a highly experienced and specialized team of technology experts in the fields of genetics, diagnostics, data and analytics, as well as a fully operational 5,000 sq. ft. genetics research and development and testing facility located in Mississauga, Ontario. Lobo also has various existing distribution and partner relationships both domestically and internationally that are a strategic fit with Entheon's goal of expanding the Lobo Platform globally.

Lobo offers a direct to consumer genetic test kit (the "**Cannabis Genetic Test Kit**") for the two main cannabinoids (1) delta-9-tetrahydrocannabinol ("**THC**") and (2) cannabidiol ("**CBD**"). The Cannabis Genetic Test Kit provides users with personalized reports and actionable insights, delivered directly to one's smartphone or desktop through the Lobo's website customer platform, providing a convenient

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and safe means to better understand one's sensitivity to THC and CBD. The test also provides insights into the short and long-term risk factors associated with THC use and how THC can affect one's memory.

The Cannabis Genetic Test Kit is available in Canada and the United States and retails for CAD\$85 in Canada and USD\$85 in the United States.

#### PROGRAMS

#### Entheon RX™

Entheon RX<sup>™</sup> Focuses on the development of therapeutic drugs using DMT as pharmacological benchmark. EBRX-101 refers to the planned DMT Phase I study and protocol described above. Additional novel molecules based on DMT structural properties have been designed in collaboration with NuChem Sciences Inc. ("**NuChem**"), a CRO based in Quebec, Canada. The company is exploring partnerships with synthetic chemistry groups able to produce these compounds for further characterization and patent development. See below under the heading "*UPDATES ON RESEARCH STUDIES*.".

#### Entheon IQ™

Entheon IQ<sup>TM</sup> focuses on the development of treatment algorithms through the analysis of patient data. EBIQ-101 refers to an observational trial currently underway at Heading Health in Austin, Texas, United States, discussed in detail below. This study is collecting genetic and EEG data from patients undergoing treatment for major depressive disorder, which will support the Company's ongoing biomarker development program. Data will be analyzed in collaboration with the Company's subsidiary, Lobo genetics, as well as with Divergence Neuroscience, a partner CRO specializing in machine learning-based EEG data analysis. See below under the headings "*EEG Project Expansion*" and "*EEG & Ketamine R&D*".

#### Entheon ID™

Entheon ID<sup>TM</sup> focuses on the identification, analysis, and predictive use of EEG biomarkers and genetics in the selection and management of drug treatment. Entheon ID<sup>TM</sup> will incorporate discoveries made in the EBRX-101 and EBIQ-101 clinical trials to support future studies that use novel biomarkers to screen patients and guide treatment protocols. See below under the headings "*EEG Project Expansion*" and "*EEG & Ketamine R&D*".

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#### OTHER BUSINESS ACTIVITIES

#### EEG Project Expansion

Entheon is actively developing EEG monitoring as a tool for real-time assessment of brain activity, to be integrated into the DMT Protocol and other treatment programs. Initially, EEG monitoring will help onsite clinicians assess a patient's subjective experience, by transmitting sensitive measurements of neuronal signal strength and complexity that have been established as correlates of psychedelic immersion. From this research and data gathering initiative the objective will be to increase Entheon's ability to develop therapies that are specific and responsive to an individual patient's needs. Pilot studies are being planned for collecting baseline EEG data in existing ketamine clinics, as described below. In partnership with Divergence Neuro Technologies Inc. ("**Divergence**"), Entheon will also apply machine learning algorithms to its growing body of EEG datasets to reveal underlying neuronal phenotypes of both the "psychedelic brain" and the "addicted brain", thus providing powerful insights into patient variability and individual sensitivity to treatment. By integrating subjective EEG data and other biomarkers with its drug delivery system in real time, Entheon's approach will yield a personalized patient experience with unprecedented safety.

#### Digital Experience Development

Entheon has decided to cease developing Virtual Reality (**\*VR**<sup>\*</sup>) and Augmented Reality (**\*AR**<sup>\*</sup>) based digital products to aid in the psychedelic-assisted psychotherapy preparation, treatment, and integration process. Though Entheon believes in an eventual future use case for audio-visual stimulus paired with neuro-technology, it is focussing its efforts on EEG-based biomarkers across a variety of mental health conditions and specific to a variety of therapeutic drug states to aid in physician awareness and monitoring.

#### EEG & Ketamine R&D

Entheon has participated in a Series A Preferred stock financing, investing \$200,000 USD for a 5% stake in Heading Health, LLC ("**Heading Health**"), which will provide R&D benefits to Entheon, including increased exposure to the ketamine-assisted therapy space and greater access to raw patient data in order to inform Entheon's in-development EEG and patient-monitoring platform.

Founded in Austin, Texas, Heading Health provides a full-suite of therapies and diagnostic tools, including Spravato® (esketamine) nasal spray and Intramuscular (IM) ketamine designed to target depression, anxiety, PTSD and OCD indications.

The Heading Health management team is experienced in operating and scaling psychiatric clinics across multiple states, securing insurance coverage and pioneering the most efficient and effective breakthroughs in clinical research and technologies.

On October 22, 2021, the Internal Review Board approved the Company's observational study with Heading Health, assessing the neurophysiological effects of ketamine. The study will gather EEG biomarker data and patient experience insight from individuals receiving ketamine therapy. Site initiation has been completed and enrollment is ongoing, with the first patient session initiated in February, 2022. The study population will be composed of participants who have been diagnosed with treatment-resistant Major Depressive Disorder and have been determined to have a medically

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appropriate indication for intramuscular ketamine treatment. The participants are also willing to wear an EEG headset which will measure brainwave patterns. The study serves as the research foundation for two divisions of the company, Entheon ID<sup>TM</sup>, focused on identification, analysis and predictive use of EEG biomarkers and genetics in the selection and management of drug treatment; and Entheon IQ<sup>TM</sup>, focused on the development of treatment algorithms through the analysis of patient data. The study will observe the EEG pattern of participants being treated with intramuscular ketamine. The data collected will be used to inform the understanding of brain activity changes in response to ketamine. In addition, genetic markers across participants will be compared, with data on impact of genetic markers and response to ketamine also being analyzed. Based on the two hypotheses being tested, that the clinical response to drug treatment can be accurately assessed during ketamine administration, and EEG changes can predict long term response to drug treatment. The Company intends to develop a framework of understanding for characterizing the psychedelic drug state of patients and to research phenotypes associated with particular addictions and mental health disorders.

In addition, an agreement has been signed with Wavepaths Ltd. ("**Wavepaths**"), a company that collaborates with world-class artists to develop adaptive music for use during psychedelic therapy. Pursuant to the agreement, Wavepaths has provided the Company with audio for ketamine therapy sessions conducted at Heading Health as part of the observational study. The Wavepaths' audio tracks will be used to control EEG variables related to patient-selected music typically used during treatment. This data set may serve as a baseline which the Company will build on to explore the impact of music on therapeutic outcomes in subsequent studies.

#### **UPDATES ON RESEARCH STUDIES**

On November 27, 2020, Psygen successfully completed the production of a non-GMP certified DMT research batch for delivery to Leiden University Medical Center ("LUMC"), CHDR's partner pharmacy. The non-GMP certified DMT research batch was shipped to LUMC on March 9, 2021. LUMC is not a related party to the Company. Some formulation and assay development work was conducted by LUMC with the Psygen non-GMP certified DMT research batch. Additional non-GMP certified DMT for further formulation and assay work together with the GMP certified DMT that will be used in the Phase I Study, as well as all related formulation and stability work, has been provided by Laboratorium Ofichem B.V. ("Ofichem") pursuant to Ofichem Services Agreement as described in the Company's AIF under the heading "General Development of the Business – History - Events Prior to Previous Fiscal Year Ended March 31, 2020." The non-GMP certified DMT substance was sent by Ofichem and received by LUMC in September 2021. Production of GMP certified DMT was completed by Ofichem and was shipped from Ofichem to LUMC on November 24, 2021. Formulation and stability testing of the GMP certified DMT by LUMC is ongoing in preparation for EBRX-101, a study that will evaluate the pharmacodynamics, pharmacokinetics and safety of a target controlled intravenous infusion of N, N-DMT in a population of healthy smokers. The Company submitted its regulatory package to the Dutch ethics committee on January 3, 2022 for its upcoming human trial, and received study approval on January 28, 2022.

As discussed in the Company's AIF under the heading "*Description of the Business - Clinical Developments*" a clinical study protocol relating to a phase II study is actively under development in collaboration with Johns Hopkins University and Imperial College of London Advisors. The Company is in ongoing discussions with scientific advisors for the phase II study, but it is not estimated to occur until 2023. The cost of the phase II study will depend on the number of clinical sites, total number of

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subjects and study design, but is currently estimated to be approximately USD\$2 million to USD\$3 million.

As discussed in the Company's AIF under the heading "General Development of the Business - Events Subsequent to Fiscal Year Ended November 30, 2020," Entheon entered into an agreement with Science in Action, to perform basic toxicity assays with DMT. On February 22, 2021, both Entheon and Science in Action applied for the requisite permits in order to export, receive and research DMT drug product. Science in Action, after securing the "hold and use" license applied and received an import permit from the Israeli authorities to import DMT for preclinical research purposes in July 2021. On August 6, 2021, a Health Canada export permit was granted for shipping Psygen's non-GMP certified DMT for acute intravenous toxicity assays. On October 11, 2021, Psygen shipped non GMP certified DMT to Science in Action pursuant to such export permit. Using this drug substance Science in Action conducted a limited acute intravenous toxicity assay in rodents. This work was completed in December 2021. The Company engaged Eurofins Discovery, which performed in vitro cardiovascular safety assays, using commercially available DMT.

As discussed in the Company's AIF under the heading "Timing and Stage of Research and Development - Stability Testing" Entheon will need to complete stability testing of the DMT Products at an approximate cost of \$20,000. Prior to commencement of clinical trials, the stability of DMT Products in the appropriate dose formulation (e.g., in sterile ampules of solution for intravenous administration) was assessed over a period of several months. By way of an update, LUMC received the non-GMP certified DMT substance this September 2021 and has commenced stability work, with approximately two months of stability testing included in the Company's investigational medicinal product dossier ("IMPD"), which is a compilation of product related data including summaries of information related to the quality, chemistry, manufacture and control of the product, data from nonclinical and clinical studies, preclinical data from existing literature and internal studies and informed consent forms. In this case, chemical manufacturing and control data for both the raw drug substance and the formulated drug product, including stability studies, comprises the bulk of the IMPD. The IMPD is part of the submissions to regulatory authorities and used, in part, to provide such regulatory authorities with confidential and detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing the DMT Product. Stability testing will continue throughout 2022 with Ofichem-supplied GMP certified DMT substances, and data will be provided to the Dutch review board on an ongoing basis. As discussed in further detail below under the heading "Use of Proceeds – Milestones and Business Objectives," by way of an update, the Phase I Study commenced in with the first patient dosed in March 2022.

As discussed in further detail in the Company's AIF under the heading "*Description of the Business -Summary of the Research and Development Process*," the Company is in the process of preparing certain regulatory documentation for submission to regulatory authorities. In specific and as of the date hereof, the Company prepared the following documents for review by Dutch regulators: (i) an IMPD, which, as mentioned above, is a compilation of product related data including summaries of information related to the quality, chemistry, manufacture and control of the product, data from nonclinical and clinical studies, preclinical data from existing literature and internal studies and informed consent forms; (ii) an Investigator's Brochure, which is a compilation of the clinical and nonclinical data on the investigational product that are relevant to the study of the product in human subjects; and (iii) a Clinical Protocol, which is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial) and ensures the safety of the trial subjects and integrity of the data. Documents related to phase II trials

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and beyond for submission to FDA, Health Canada, or EMA have not been prepared, as they will be dependent on the results of the Phase I Study. The Company submitted its regulatory package to the Dutch ethics committee on January 3, 2022 and received study approval on January 28, 2022.

#### EVENTS AND TRANSACTIONS

For the year ended November 30, 2021, Entheon has expended \$8,886,555 on development of its business. As at November 30, 2021, Entheon had a working capital of \$2,280,792. During this time Entheon's activities have focused on

- negotiating and executing strategic investments;
- conducting private placement financings;
- engaging partners to assist with the design and development of Entheon's *EEG Project Expansion*;
- engaging consultants to assist with the design and development of Entheon's *Digital Experience Development*;
- entering into a business arrangement with Heading Health and sponsorship of a clinical research study to further the development of Entheon's *EEG & Ketamine R&D*;
- negotiating and executing the acquisition of HaluGen to commercialize a pre-screening test to identify genetic markers predictive of an individual's reaction to hallucinogenic drugs;
- recruiting experienced leaders and advisors with senior pharma experience;
- negotiating and executing the Ofichem Services Agreement;
- uplisting from the OTC Pink to the OTCQB Venture Market, under the symbol "ENTBF";
- negotiating and executing the acquisition of Lobo in order to further the development of Entheon's EEG Project Expansion;
- launching the sale of the Psychedelics Genetic Test kit in Canada and the United States;
- entering into referral agreement partnership to help drive brand awareness of the Psychedelics Genetic Test kit;
- filing the AIF for the year ended November 30, 2020;
- filing the Preliminary Short Form Base Shelf Prospectus; and
- obtaining eligibility for electronic clearing and settlement through the Depository Trust Company ("**DTC**") in the United States.

On December 4, 2020 the Company executed an investor relations consulting agreement with Joseph Cullen, pursuant to which the Company has agreed to pay Mr. Cullen a sum of \$5,000 per month for a one-year term. In addition, pursuant to its stock option plan, Entheon granted options to purchase up to 3,175,000 Common Shares (the **"Options"**) to certain officers, directors and consultants of the Company. The Options are exercisable at \$0.71 per share for a period of five years from the date of grant. Of the Options, 2,725,000 are subject to graded vesting over a 2-year term, with 25% vesting every 6 months and the remaining vesting immediately. The Options have been granted under and are governed by the terms of Entheon's incentive stock option plan.

On December 9, 2020, the Company elected to exercise its option to purchase up to 9.9% of the common shares of 2756407 Ontario Inc. dba Wonder Scientific ("**Wonder Scientific**"). The Company paid an aggregate purchase price of \$150,000 to acquire 937,500 shares of Wonder Scientific at an option exercise price of \$0.16 per common share.

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On December 10, 2020, the Company signed a share purchase agreement with Wonder Scientific, the securityholders of Wonder Scientific ("**Vendors**"), and Global Health Clinics Ltd. ("**Global Health**") whereby the Vendors shall sell, assign, and transfer to Global Health, and the Global Health shall purchase from the Vendors, all of the right, title, and interest in 100% of the issued and outstanding common shares of Wonder Scientific ("**Purchased Shares**"), free and clear of all adverse interests. Upon closing the Company received 2,260,870 common shares of Global Health. Global Health operates a two-part system of customer lead generation and conversion, through its network of pavilions and the ownership and operation of five medical clinics that aim to connect Canadians with ACMPR license producers by advancing the understanding of medical cannabis and its applications, and the provision of related services and products for patients suffering from illness from which they may find relief with medical cannabis, including facilitating access to qualified health care practitioners, independent medical cannabis evaluations and related advice. Global Health is traded on the CSE under the trading symbol "MJRX".

On December 24, 2020, the Company completed the first tranche of a non-brokered private placement financing for total gross proceeds of \$3,174,374 (the "December 2020 Placement"). The majority of the December 2020 Placement was subscribed for by strategic investors. The Company has allotted and issued 4,232,499 units (the "December Units") at a price of CAD\$0.75 per December Unit. Each December Unit is comprised of one Common Share and one-half of one non-transferable common share purchase warrant ("Entheon Warrant"). Each Entheon Warrant entitles the holder to purchase one additional Entheon Share for a period of two (2) years at a price of \$1.00 per Common Share, subject to accelerated expiry. In the event that, after four months and one day from issuance, the Common Shares trade at a closing price at or greater than \$1.50 per Common Share for a period of 10 consecutive trading days, the Company may accelerate the expiry date of the Entheon Warrants by giving notice to the holders thereof, and in such case, the Entheon Warrants will expire on the 30th day after the date on which such notice is given by the Company (the "Acceleration Right"). Additionally, in connection with the December 2020 Placement, the Company paid finder's fees totaling \$126,367 and issued an aggregate 168,490 finder's warrants to arm's-length parties. Each finder's warrant is exercisable into one December Unit for a period of up to two years at a price of \$0.75. The Company also paid other share issuance costs of \$4,778 in cash.

On January 4, 2021, as discussed above, the Company entered into a business arrangement with, and made a strategic investment in, Heading Health, a psychiatric clinic platform focused on the administration of psychedelic-assisted therapy to treat mental health disorders. In connection therewith, the Company and Heading Health executed a letter of intent. Entheon participated in a Series A Preferred stock financing, investing USD \$200,000 (CDN \$255,760) for a 5% stake in Heading Health. Under the terms of the investment, Entheon has the option, which it intends to exercise, to increase its overall holdings to up to 10% of Heading Health in the subsequent round of financing. This investment into Heading Health provides Entheon with exposure to the ketamineassisted therapy space, including Spravato, an FDA approved Ketamine product that is eligible for insurance reimbursement. This business arrangement allows access to data pertaining to ketamine therapy and the patient experience. This data will be used for research purposes to better inform the development of Entheon's own psychedelic therapy experience. Heading Health will provide guidance regarding clinical practice and the use of biomarker capture devices both in general psychiatric practice and Ketamine treatments. The arrangement is subject to the execution of a definitive agreement by both parties. See above under the heading "Other Business Activities - EEG & Ketamine R&D."

Fiscal year ended November 30, 2021

On January 11, 2021, the Company engaged Scott Keeney (known as DJ Skee, an American artist, television host, radio personality, philanthropist and entrepreneur) to serve as a media advisor. In his role, Mr. Keeney will work directly with the CEO of the Company, Timothy Ko, to develop multimedia campaigns and experiences specifically designed to define Entheon's role in the emerging psychedelic drug industry. Furthermore, Entheon seeks to utilize Mr. Keeney's experience in technology and platform building to explore the creation of media experiences for the purposes of enhancing and supporting psychedelic-assisted therapy patients. See above under the heading "Other Business Activities – Digital Experience Development".

On January 11, 2021, the Company closed a second tranche of the December 2020 Placement for additional proceeds of \$40,141. Pursuant to this second tranche, the Company allotted and issued 53,521 December Units, all of which are also subject to the Acceleration Right.

On January 14, 2021, the Company completed its acquisition of HaluGen. See below under the heading "*Acquisition of HaluGen Life Sciences Inc.*".

On January 19, 2021, the Company announced a partnership with Divergence, a company focused on the focused on the research and development of a data-driven, cloud-based neuro platform based on EEG analysis and machine learning, to research and develop DMT biomarkers and a predictive model of biomarker responses to drug dosage and delivery of DMT-based psychedelic therapeutic products targeted to treat a number of different addiction and substance use disorders (the "**DMT Biomarker Model**"). Divergence will also develop a software platform that supports the tracking of EEG data during pre, intra, and post dosing using, among other prediction models, the DMT Biomarker Model. See above under the heading "Other Business Activities – EEG Project Expansion".

On February 4, 2021, the Company announced that it had appointed Joanna Birgans as Vice President of Digital Experience. Ms. Birgans will oversee and coordinate the creation of audio-visual and virtual reality-based experiences designed to enhance and modify the psychedelic therapy experience, while also leading the production of original company media content. See above under the heading "*Other Business Activities – Digital Experience Development*".

On February 16, 2021, the Company announced that it had appointed Dr. Brian Jahns to the role of Chief Business Officer. Dr. Jahns brings more than 20 years of business leadership and biopharmaceutical expertise to his role in overseeing the overall business development of Entheon, including the development and maintenance of strategic relationships with third parties, including regulatory authorities. Importantly, Dr. Jahns will also work to develop a commercialization and post-market strategy for Entheon's therapeutic protocols, while developing and advancing other related products, services, and initiatives of the company. Dr. Jahns has held senior leadership roles in the biopharmaceutical industry, including ZYUS, Trillium Therapeutics and Roche Canada, and has been deeply involved in the successful launch and growth of several successful compounds including antiviral agents, transplant drugs and anticancer biologics and developing targeted therapies for previously untreated diseases. Dr. Jahns has led preparations for commercialization, led efforts to procure commercial scale manufacturing, and led business partnering activities for several compounds.

On February 22, 2021, Entheon engaged Nancy Maher as Special Advisor of Data Science and Regulatory Affairs, providing expertise on the development of Entheon's data strategy design, study design and advise on regulatory relationships and data strategy. Ms. Maher has served as an

Fiscal year ended November 30, 2021

executive and consultant for major pharmaceutical and information technology companies, including IBM, Gilead, Schering-Plough, Merck, Allergan, and Teva Pharmaceuticals and is currently SVP, Chief Information Officer, North America of Kyowa Kirin International plc. Ms. Maher will be consulting on the development and implementation of Entheon's data management systems for the collection, organization and analysis of data from upcoming pre-clinical and clinical trials, partnership initiatives, private clinic partnerships, and various technological initiatives. In addition, Ms. Maher will inform Entheon of best practices for the design and implementation of security measures as they relate to Entheon's data program, while also informing regulatory strategy and relationship as it relates to advancing conversations and applications with Health Canada, the FDA and EMA regulatory authorities.

On February 22, 2021, the Company announced ethics approval for an upcoming pre-clinical study to be conducted by the CRO, Science in Action, an Israeli-based lab specializing in pre-clinical in vivo and in vitro R&D services. Science in Action has confirmed that it has received ethics approval for an in vivo non-GLP toxicology study of DMT (the **"Science in Action Study"**). Both Entheon and Science in Action have applied for requisite permits in order to export, receive and research DMT drug product. The objective of the Science in Action Study is to determine the acute toxicity of IV doses of DMT in a 14-day in vivo study. The Science in Action Study is being performed in advance of the Company's human studies to evaluate DMT's pharmaco-therapeutic profile for the treatment of substance-use disorder.

On February 24, 2021, Entheon announced that HaluGen's proprietary Psychedelics Genetic Test Kit and technology platform had completed research and development and is nearing commercial production.

On February 25, 2021, Entheon allotted and issued 900,000 Common Shares to Lobo for fulfilling its performance milestone in accordance with a Product Development Agreement among Entheon, HaluGen and Lobo. The shares are subject to a hold period of four months and one day.

On March 10, 2021, the Company engaged Shimon Lecht, PhD., currently Chief R&D Officer at CannRX, as preclinical project leader. Lecht will act as a direct liaison with Science in Action, the Israeli-based CRO which is preparing to carry out a 14-day in vivo toxicology study of DMT. Previously of Izun Pharmaceuticals & Ci Therapeutics, Dr. Lecht has extensive expertise in interdisciplinary preclinical and clinical drug R&D, and the management of large-scale projects related to drug candidate screening, pre-clinical proof-of-concept studies, human clinical trials, and in leading interactions with regulatory agencies.

On April 6, 2021, the Company announced that HaluGen's psychedelics genetic test kit was now available for sale in the Canada for CAD\$89.

On May 3, 2021, the Company engaged Grant Galloway and Christopher Biggin from CannaCapFund.com to provide investor relations services. Pursuant to an independent consulting agreement, the Company shall pay a fee of USD\$25,000 per month for a three-month term, and shall have the option to continue the services at a rate of USD\$12,500 per month for an additional six-month term thereafter.

On May 4, 2021, the Company entered into the Ofichem Services Agreement with Laboratorium Ofichem B.V. ("**Ofichem**"). Under the terms of the Ofichem Services Agreement, Ofichem will

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synthesize, validate, and produce for Entheon GMP quality DMT for use in clinical phase I studies. Ofichem has been contracted by Entheon as a secondary source of DMT at a cost of €98,520.

On May 5, 2021 the Entheon Shares began trading on the OTCQB Venture Market under the symbol "ENTBF."

On June 1, 2021, the Company engaged Dr. Dinesh Bhayana, Board Member of MAPS Canada with extended training and experience in the application of Ketamine-Assisted Psychotherapy, as an advisor to provide guidance to the Company regarding therapeutic practices, product development and clinical trial design.

On June 10, 2021, the Company announced that HaluGen's psychedelics genetic test kit was now available for sale in the United States for USD\$89.

On June 15, 2021, the Company entered into an amalgamation agreement with Lobo Genetics Inc. and 13089363 Canada Inc. See disclosure under the heading "*Acquisition of Lobo Genetics Inc.*" for more information on the acquisition of Lobo.

On June 17, 2021, the Company announced a referral agreement partnership with Silo Wellness Inc. (CSE: SILO) (OTC: SILFF) (FSE:3K70) ("**Silo Wellness**"), a functional and psilocybin mushroom company and psychedelic wellness retreats operator, to help drive brand awareness of the Psychedelics Genetic Test kit, developed by HaluGen.

On June 22, 2021, the Company announced a referral agreement partnership with 3W Wellness Inc. ("**Third Wave**"), an organization committed to sharing trusted, research-based content and resources for safe, structured, and responsible psychedelic us, to help drive brand awareness of the Psychedelics Genetic Test kit, developed by HaluGen.

On June 24, 2021, the Company filed an AIF for the year ended November 30, 2020 with the applicable securities commissions.

On June 25, 2021, the Company announced a referral agreement partnership with Maya Health PBC ("**Maya**"), a company that has developed a measurement-based care platform designed to support psychedelic practitioners and patients, to help drive brand awareness of the Psychedelics Genetic Test kit, developed by HaluGen.

On July 22, 2021, the Company engaged Dr. Andrew Greenshaw, Professor of Psychiatry and Neuroscience and Associate Chair (Research) for Psychiatry at the University of Alberta, as an advisor to provide guidance to the Company regarding therapeutic practices and clinical trial design.

On July 29, 2021, the Company completed its acquisition of Lobo, its now wholly-owned subsidiary, and John Lem, the founder and CEO of Lobo joined Entheon's advisory board as a strategic advisor of industry affairs. See disclosure under the heading "*Acquisition of Lobo Genetics Inc.*" for more information on the acquisition of Lobo.

On July 30, 2021, the Company filed a Preliminary Short Form Prospectus with the applicable securities commissions.

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On August 12, 2021, the Company announced the sponsorship of a clinical research study with Heading Health as institution and Dr. Steve Levine, MD, as principal investigator to determine the electroneurophysiologic effects of ketamine.

On August 13, 2021, the Company engaged Dr. David Erritzoe, Clinical Director of Imperial College's Center for Psychedelic Research, as an advisor to provide guidance to the Company regarding therapeutic practices and clinical trial design.

On August 24, 2021, the Company announced that its common shares are now eligible for electronic clearing and settlement through the DTC in the United States.

On August 25, 2021, the Company announced that Dr. David Erritzoe, the current Clinical Director of the Imperial College's Center for Psychedelic Research, had been appointed to Entheon's Advisory Board.

On October 22, 2021, the Company received approval from the Internal Review Board for the EBIQ-101 observational study.

On November 10, 2021, the Company announced that recruitment had begun for the EBIQ-101 observational study.

On November 11, 2021, the Company granted 1,150,000 restricted share units (the "**RSUs**") to consultants of the Company. The RSUs are valid for a three-year term and are governed by the Company's RSU Plan, approved by the Company's directors on October 20, 2021 and subject to shareholder approval at the upcoming Annual General Meeting on November 19, 2021.

#### **RESULTS OF OPERATIONS**

#### Overview

Entheon's total assets as at November 30, 2021 were \$9,977,712 (\$4,473,072 - November 30, 2020), a difference of \$5,504,640. The increase was primarily as a result of the acquisition of intangible assets through the acquisition of HaluGen and Lobo. Entheon's current liabilities as at November 30, 2021 were \$927,713 (\$728,192 – November 30, 2020), a increase of \$199,521, primarily due to the timing of payments of accounts payable. Entheon had cash at November 30, 2021, in the amount of \$2,049,131 (\$2,787,006 – November 30, 2020) and working capital of \$2,280,792 (\$3,676,241– November 30, 2020). The decrease in cash was primarily due to funding operations and the decrease in working capital was primarily due to the decrease in cash and amortization of prepaid expenses.

In comparing Entheon's financial condition for the year ended November 30, 2021, in comparison to the year ended November 30, 2020, industry factors are substantially unchanged. As at November 30, 2020, Entheon's operations were impacted by COVID-19 due to social distancing requirements, lock-downs and travel restrictions. While circumstances appeared to improve in 2021, the restrictions on Entheon's operations during the year ended November 30, 2021 had begun to fade out comparison to the circumstances at November 30, 2020. Nonetheless, the pace of economic recovery once COVID-19 is under control cannot accurately be predicted and may be slow. Additionally, it is possible for restrictions to be reimposed in the event case counts begin to rise again. The full impact of the COVID-19 pandemic continues to evolve at the date of this report. The length and continued impact

Fiscal year ended November 30, 2021

of COVID-19 across the globe is unknow. See "*Risk Factors – Impact of COVID-19*" for more information.

#### Research and development

Research and development expenses consist of the following:

|                                  | For the year ended Nov 30,<br>2021 | For the year ended Nov 30,<br>2020 |
|----------------------------------|------------------------------------|------------------------------------|
|                                  | \$                                 | \$                                 |
| Clinical research and regulatory | 432,233                            | -                                  |
| Digital experience development   | 148,607                            | -                                  |
| EEG project expansion            | 529,663                            | -                                  |
| Management, consulting, payroll  | 303,093                            | 377,124                            |
| Professional fees                | 81,364                             | 65,436                             |
|                                  | 1,494,960                          | 442,560                            |

The Company recorded research and development expenses for the year ended November 30, 2021 of \$1,494,960 compared to research and development expenses for the year ended November 30, 2020 of \$442,560, an increase of \$1,052,400, primarily due to advancing the development of the DMT Products and DMT Delivery System as well as commencing the development of the Digital Experience and EEG project expansion.

#### General and administrative

General and administrative expenses consist of the following:

|                                 | For the year ended Nov 30, | For the year ended Nov 30, |  |
|---------------------------------|----------------------------|----------------------------|--|
|                                 | 2021                       | 2020                       |  |
|                                 | \$                         | \$                         |  |
| Management, consulting, payroll | 1,223,084                  | 654,621                    |  |
| Marketing and travel            | 2,200,029                  | 305,532                    |  |
| Professional fees               | 315,754                    | 81,722                     |  |
| Office and insurance            | 709,103                    | 134,196                    |  |
| Transfer agent and filing fees  | 132,341                    | 19,406                     |  |
|                                 | 4,580,311                  | 1,195,477                  |  |

The Company recorded general and administrative expenses for the year ended November 30, 2021 of \$4,580,311 compared to general and administrative expenses for the year ended November 30, 2020 of \$1,195,477, an increase of \$3,384,834, primarily due the addition of management and consultants to support the growth of the business, the purchase of insurance, and the execution of several large marketing campaigns aimed at building awareness of the Company's brand and novel status as a publicly traded biosciences company in the psychedelic space.

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#### Select annual information

The following table provides select annual information:

|  | For the year ended Nov<br>30, 2021 | For the year ended<br>Nov 30, 2020 |
|--|------------------------------------|------------------------------------|
| Net loss and comprehensive loss                      | \$8,886,555                        | \$4,381,491                        |
| Basic and diluted loss per share                     | \$0.16                             | \$0.16                             |
| Weighted average number of common shares outstanding | 54,285,133                         | 27,439,935                         |

During the year ended November 30, 2021, Entheon reported a net loss of \$8,886,555 compared to a net loss of \$4,381,491 for the year ended November 30, 2020. The increase in the loss was attributable to the activities discussed under "*Events and Transactions*" above.

#### Summary of quarterly results

|                       | Nov 30,<br>2021 | Aug 31,<br>2021 | May 31,<br>2021 | Feb 28,<br>2021 | Nov 30,<br>2020 | Aug 31,<br>2020 | May 31,<br>2020 | Feb 29,<br>2020 |
|-----------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                       | \$              | \$              | \$              | \$              | \$              | \$              | \$              | \$              |
| Total revenue         | 14,314          | 5,899           | 1,457           | Nil             | Nil             | Nil             | Nil             | Nil             |
| Net loss              | 1,869,789       | 1,719,149       | 2,413,980       | 2,883,637       | 3,290,429       | 350,663         | 371,552         | 368,847         |
| Loss per share        | 0.03            | 0.03            | 0.04            | 0.06            | 0.11            | 0.01            | 0.02            | 0.02            |
| Loss per share        | 0.03            | 0.03            | 0.04            | 0.06            | 0.11            | 0.01            | 0.02            | 0.02            |
| (fully-diluted)       |                 |                 |                 |                 |                 |                 |                 |                 |
| Cash                  | 2,049,131       | 3,382,955       | 4,107,042       | 5,022,241       | 2,787,006       | 1,840,612       | 946,897         | 427,085         |
| Working capital       | 2,280,792       | 3,562,288       | 4,889,508       | 6,266,714       | 3,676,241       | 1,880,765       | 938,853         | 538,846         |
| Total assets          | 9,977,712       | 10,403,435      | 10,089,985      | 12,033,985      | 4,473,072       | 2,036,394       | 1,123,460       | 678,491         |
| Total non-current     | Nil             |
| financial liabilities |                 |                 |                 |                 |                 |                 |                 |                 |

The variability of net loss during the quarterly results is mainly due to the expenses described above in the "*Results of Operations*" section. Additionally, as a result of the commercialization of HaluGen's Psychedelics Genetic Test and Lobo's Cannabis Genetic Test Kits, the Company began generating revenue during the year ended November 30, 2021 (Revenue \$Nil – November 30, 2020).

#### **Milestones and Business Objectives**

Set out below is an update to the Company's milestones:

| Milestone  | Update  |
|--|---|
| Obtaining the Drug<br>Products from Psygen<br>for nonclinical and<br>clinical trials (now, | Psygen Labs completed a non-GMP research batch of DMT fumarate for Entheon in December 2020. A portion of this material was sent to the clinical pharmacy in the Netherlands (LUMC) in March 2021 for formulation and analytical assay development, after obtaining import permits from the Netherlands and export permits from Health Canada. Additional material has been earmarked for preclinical studies to be conducted in Israel, which commenced in December 2021. As at the date hereof, Entheon had |

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| Sourcing the Drug<br>Products – Psygen) | expended USD\$2,500 towards this milestone, leaving USD\$37,500 remaining from the figure referenced in the Listing Statement. Entheon does not anticipate expending additional funds towards this milestone over the next 12 months.  |
|---|--|
| Sourcing the Drug<br>Products - Ofichem | The Company expects to spend €98,520 on sourcing DMT from Ofichem pursuant to the Ofichem Services Agreement. To avoid regulatory delays in GMP drug procurement related to permitting and the international shipping of controlled substances, as well as to mitigate uncertainty due to the Covid-19 pandemic, a secondary source of GMP certified DMT fumarate was established in early 2021 within the Netherlands from Ofichem, a manufacturer and distributor of active pharmaceutical ingredients. The Company selected Ofichem because obtaining the GMP drug substance from a manufacturer within the same country as the Phase I Study has the advantage of circumventing the need for import/export permitting, saving months of regulatory lead time. Although Entheon is using the Psygen material for certain preclinical studies, Ofichem has been selected to provide GMP certified DMT and non-GMP certified DMT substance to LUMC for formulation and stability studies in early September 2021; additionally, Ofichem shipped the GMP certified DMT substance to LUMC November, 2021. As at the date hereof, Entheon had expended EUR€98,520 towards this milestone, leaving EUR€Nil remaining. |
| Conducting the<br>Preclinical Studies   | The amount expected to be spent on this milestone had been updated from \$88,159 (as listed in the Listing Statement) to \$50,000. Limited preclinical assays to support the Phase I Study application have been completed. These include an acute intravenous toxicity assay, which was completed in December 2021 at Science in Action, an Israel-based CRO. Additional cell-based assays to assess genotoxicity (Ames test) and cardiac channel interactions (hERG assay) by Eurofins Discovery was completed in the United States in November 2021. As at the date hereof, Entheon had expended \$40,354 towards the milestone, leaving an estimated \$9,646 remaining.  |
| DMT formulation<br>development          | The clinical pharmacy, LUMC, obtained an initial sample of non-GMP certified DMT fumarate from Psygen Labs in March 2021. With this material, LUMC has developed a basic drug product formulation and has also developed analytical assays to accurately measure drug concentration and purity on-site. This formulation work was validated and carried forward by LUMC with non-GMP certified DMT fumarate which was received by LUMC from Ofichem in September 2021. LUMC continued this work with GMP certified DMT fumarate upon receipt of such drug substance from Ofichem, which Ofichem shipped to LUMC in November 2021. Cost estimates are included in the pharmacy estimates under the milestone "Developing the DMT Protocol and Conducting the Phase I Study." As such, this milestone has been removed.  |
| DMT Assay<br>Development                | Analytical method development using DMT drug substance from Psygen Labs was completed at LUMC, the clinical pharmacy located in the Netherlands in Q2 2021, as described above. Additional validation of these assays was performed using the Ofichem-supplied non-GMP certified DMT drug substance which was received by LUMC in September 2021 and using the Ofichem-supplied GMP certified DMT drug substance which was shipped to LUMC in November 2021. Stability studies will be ongoing for at least 6 months, concurrent with the Phase I Study. As at the date hereof, Entheon had expended \$Nil towards the milestone. The estimate has been updated from \$100,000, being the figure referenced in the Listing Statement to EUR€66,050 (approximately CDN\$92,906).  |
| Clinical Trial Insurance                | Entheon acquired clinical trial insurance in Februray 2022 following the finalization of the Phase I Study protocol and receipt of the informed consent forms by CHDR. As at the   |

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|  | date hereof, Entheon has expended \$12,862 towards this milestone, leaving \$Nil remaining.   |
|--|---|
| Developing the DMT<br>Protocol and Conducting<br>the Phase I Study<br>(EBRX-101) | The DMT Protocol (as defined herein) has been completed and submitted as part of the clinical trial application to the Dutch Ethics Committee, and is largely based on the details of continuous intravenous administration of DMT fumarate to humans. The DMT Protocol synopsis was finalized in June 2021 and an initial draft of the full DMT Protocol was received by the Company in late September 2021. The second draft of the full DMT Protocol was sent to CHDR for review by its Scientific Advisory Board on October 12, 2021; the Scientific Advisory Board has completed their review and has provided their endorsement of the second draft. The Company submitted its regulatory package to the Dutch ethics committee on January 3, 2022. and received approval on January 28, 2022. The Phase I Study based on the DMT Protocol commenced with the first patient dosed in March 2022. Each of five cohorts of 10 subjects will be conducted sequentially in an adaptive, single ascending dose study design. Data will be analyzed after each cohort to allow for the adjustment of dosing and safety parameters prior to dose escalation for the following cohort. As at the date hereof, Entheon had expended EUR€240,138 towards the completion of this milestone, leaving EUR€903,350 and CDN\$76,083 remaining. |

#### **Updated Milestone Commitments**

Set forth below are Entheon's updated commitments for milestone expenditures over the next twelve months.

| Commitment                                     | Estimated Cost  |
|--|---|
| Conducting the Preclinical Studies             | \$9,646   |
| DMT Assay Development                          | €66,050 (CDN\$91,083) <sup>(1)</sup>  |
| Developing the DMT Protocol and Conducting the | \$1,321,803 (€903,350 (CDN\$1,245,720) <sup>(1)(2)</sup> + CDN\$76,083 <sup>(3)</sup> ) |
| Phase I Study (EBRX-101)                       |   |
| Heading Health Observational Study (EBIQ-101)  | \$205,037 (USD\$138,600 (CDN\$173,874) <sup>(4)</sup> + CDN \$31,163 <sup>(5)</sup> )   |
| Other  | \$35,000 <sup>(6)</sup>   |
| Total  | \$1,662,569   |

Notes:

- <sup>(1)</sup> Based on the Bank of Canada exchange rate on March 24, 2022 of 1.3790.
- <sup>(2)</sup> Comprised of: (1) of €903,350 (CDN\$1,245,720) pursuant to the CHDR Clinical Study Agreement, and (2) CHDR Clinical Study Change Order #1.
- <sup>(3)</sup> Ancillary costs in connection with the Phase I Study.
- <sup>(4)</sup> Based on the Bank of Canada exchange rate on March 24, 2022 of 1.2545.
- <sup>(5)</sup> Ancillary costs in connection with the Heading Health Observational Study.
- <sup>(6)</sup> Comprised of (1) developing proprietary patent-protected formulations intended to improve the delivery of DMT in a patient appropriate manner, and (2) developing next-generation patent-protected drug candidates that display improved pharmacological characteristics versus a DMT benchmark.

#### LIQUIDITY AND CAPITAL RESOURCE

Entheon had cash at November 30, 2021, in the amount of \$2,049,131 and working capital of \$2,280,792 in order to meet short-term business requirements. During the year ended November 30, 2021 Entheon had the following changes in cash flow:

#### Cash used in Operating Activities

Entheon's cash used in operating activities for the year ended November 30, 2021 was \$5,615,218 compared to Entheon's cash flows used in operating activities for the year ended November 30, 2020

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of \$2,837,522, an increase of \$2,777,696, primarily due to result of an increase in operational expenses that Entheon incurred.

#### Cash used in Investing Activities

Entheon's cash used in investing activities for the year ended November 30, 2021 was \$98,866 compared to Entheon's cash provided by investing activities for year ended November 30, 2020 of \$1,082,358, a decrease of \$1,181,224. The company expended more cash on investing activities in the year ended November 30, 2021 - \$560,538 (primarily equity investments and equipment) compared to \$257,033 in the year ended November 30, 2020 (primarily investments in convertible notes and equipment). In addition, the company acquired less cash on investing activities in the year ended November 30, 2021 - \$461,672 (primarily on the acquisition of HaluGen and Lobo) compared to \$1,339,391 in the year ended November 30, 2020 (primarily on the RTO and repayment of convertible notes). As a result, the total cash used in investing activities for the year ended November 30, 2021 compared to the year ended November 30, 2020 increased.

#### Cash provided by Financing Activities

Entheon's cash provided by financing activities for the year ended November 30, 2021 was \$4,976,209 compared to Entheon's cash provided by financing activities for the year ended November 30, 2020 of \$4,429,515, an increase of \$546,694, primarily due to the exercise of warrants and non-brokered private placement financings.

In order to continue as a going concern and meet its corporate objectives, Entheon will require additional financing through debt or equity issuances or other available means. Although Entheon has been successful in the past in obtaining financing, there is no assurance that Entheon will be able to obtain adequate financing in the future or that such financing will be on terms advantageous to Entheon. Should Entheon identify a suitable asset or business acquisition, it would be required to raise additional capital to finance the transaction.

Entheon requires positive working capital to be able to continue its operations and have sufficient funds to satisfy maturing short-term obligations. Upcoming operational expenses include management and consulting fees, marketing expenses, office expenses, rent, and professional fees. Entheon also requires working capital to fund research and development.

The extent of Entheon's liquidity is dependent upon, among other things, its ability to: (a) complete subsequent debt or equity financings or obtain other sources of funding; (b) adequately manage its cash on hand; and (c) reduce costs and expenses. The aforementioned factors indicate the existence of material uncertainties which may cast significant doubt on Entheon's ability to continue as a going concern. Additionally, economic downturns, uncertainties related to the COVID-19 pandemic, changes in legislation or policies that affect Entheon and changes in the industry in which Entheon operates, in each case as discussed in more detail under the heading "*Risk Factors*", are, among others, circumstances that may affect Entheon's liquidity.

This MD&A does not discuss adjustments or accompanying information that would be required if the going concern assumption is not an appropriate basis for preparation of the financial statements related to this MD&A. These adjustments could be material.

Fiscal year ended November 30, 2021

#### SHARE CAPITAL

As at November 30, 2021 Entheon has the following outstanding securities:

- (i) Common Shares: 59,089,266
- (ii) Warrants: 8,285,940
- (iii) Stock options: 3,675,000
- (iv) RSUs: 1,150,000

As at and at the date hereof, Entheon has the following outstanding securities:

- (i) Common Shares: 59,089,266
- (ii) Warrants: 6,958,440
- (iii) Stock options: 3,225,000
- (iv) RSUs: 1,150,000

Entheon has obtained its capital funding through debt and equity financings.

#### **RELATED PARTY TRANSACTIONS**

Key management personnel comprise the Company's Board of Directors, Chief Executive Officer, Chief Financial Officer, Chief Science Officer and Director of Operations, Chief Business Officer, and Corporate Secretary. Key management personnel compensation is comprised of the following:

|  | For the year<br>ended<br>November 30,<br>2021 | For the year<br>ended<br>November 30,<br>2020 |
|--|---|---|
|  | \$  | \$  |
| Payroll, consulting fees, and other benefits | 531,351                                       | 259,743                                       |

On February 5, 2020, the Company issued a total of 100,000 common shares with a fair value of \$25,000 to settle \$2,000 in management fees payable to the Director of Operations. A loss on debt settlement of \$23,000 was recognized in the consolidated statement of comprehensive loss for the year ended November 30, 2020.

The Company had a credit facility agreement with a company controlled by the CEO and during the year ended November 30, 2020, the Company repaid amount of \$3,029 to the related party.

As at November 30, 2021, \$Nil (November 30, 2020 - \$4,570) was due to directors and officers and companies controlled by directors and officers. The amounts are unsecured, non-interest bearing, due on demand and included in accounts payable and accrued liabilities.

During the year ended November 30, 2021, the Company granted 2,075,000 options to officers and directors, with either immediate vesting or graded vesting with 25% every 6 months. The share-based compensation for these related parties totaled \$1,263,810 for the year ended November 30, 2021.

Fiscal year ended November 30, 2021

#### CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

#### Significant estimates and judgements

The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated interim financial statements and reported amounts of expenses during the period. Actual results could differ from these estimates. The Company's management reviews these estimates and underlying assumptions on an ongoing basis, based on experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Revisions to estimates are adjusted for prospectively in the period in which the estimates are revised. Significant areas requiring the use of management estimates include:

- i) The determination of discount rate and effective interest rates on liability and equity components of the convertible notes. Changes in these assumptions could materially affect the recorded amounts.
- ii) The determination of fair value of investments in convertible notes and equity securities requires valuation techniques. In applying the valuation techniques management makes maximum use of market inputs wherever possible, and uses estimates and assumptions that are, as far as possible, consistent with observable data that market participants would use in pricing the instrument. Where applicable data is not observable, company-specific information is considered when determining whether the fair value of an investment in convertible notes or equity securities should be adjusted upward or downward at the end of each reporting period. In addition to company-specific information, the Company will take into account trends in general market conditions and the share performance of comparable publicly-traded companies when valuing investments in convertible notes and equity securities.
- iii) The determination of deferred income tax assets or liabilities requires subjective assumptions regarding future income tax rates and the likelihood of utilizing tax carry-forwards. Changes in these assumptions could materially affect the recorded amounts.
- iv) The valuation of options and warrants requires estimation and assumptions for valuation techniques. Changes in such assumptions and estimates could materially impact the recorded amounts.
- v) Amortization of intangible assets are dependent upon estimates of useful lives, which are determined through the exercise of estimates. The assessment of any impairment of these assets is dependent upon estimates of recoverable amounts that take into account factors such as economic and market conditions and the useful lives of assets.

#### Significant judgments

The preparation of these consolidated financial statements requires management to make judgments, apart from those involving estimates, in applying accounting policies. The most significant judgments in applying the Company's consolidated financial statements include:

- i) The assessment of the Company's ability to continue as a going concern involves judgment regarding future funding available for its projects and working capital requirements and whether there are events or conditions that may give rise to significant uncertainty.
- ii) The determination of whether a business combination or an asset acquisition involves judgment regarding whether the acquiree meets the definition of business under IFRS 3. The application of the Company's accounting policy for business combinations requires management to make certain judgments on a case-by-case basis as to the determination of the accounting method of an acquisition to determine if the assets acquired meet the definition of a business requiring the acquisition method of accounting for a business combination test.

#### FINANCIAL RISK MANAGEMENT

The Company's financial instruments are exposed to certain financial risks, including credit risk, liquidity risk, and market risk.

#### Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The Company has exposure to credit risk through its cash and cash equivalents. The Company manages credit risk, in respect of cash, by maintaining the majority of cash at highly rated financial institutions.

The Company's maximum exposure to credit risk at the end of any period is equal to the carrying amount of these financial assets as recorded in the statement of financial position. At November 30, 2021 and November 30, 2020, no amounts were held as collateral.

#### Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulty in satisfying financial obligations as they become due. The Company manages its liquidity risk by forecasting cash flows required by its operating, investing and financing activities. The Company had cash at November 30, 2021, in the amount of \$2,049,131 and working capital of \$2,280,792 in order to meet short-term business requirements. Accounts payable have contractual maturities of approximately 30 to 90 days or are due on demand and are subject to normal trade terms.

#### Market risk

Market risk consists of interest rate risk, foreign currency risk and price risk. These are discussed further below.

#### Interest rate risk

Interest rate risk consists of two components:

i) To the extent that payments made or received on the Company's monetary assets and liabilities are affected by changes in the prevailing market interest rates, the Company is exposed to interest rate cash flow risk.

Fiscal year ended November 30, 2021

 ii) To the extent that changes in prevailing market rates differ from the interest rates on the Company's monetary assets and liabilities, the Company is exposed to interest rate price risk.
In management's opinion, the Company is not exposed to significant interest rate risk as the risk is primarily on cash and cash equivalents.

#### Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in foreign exchange rates. The Company is not subject to significant foreign exchange risk.

#### Price risk

Price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices, other than those arising from interest rate risk or foreign currency risk.

The Company is not exposed to any significant price risk.

#### Capital Management

The Company's objective when managing capital is to safeguard the Company's ability to continue as a going concern in order to pursue the research and development of psychedelic compounds.

The Company sets the amount of capital in proportion to risk. The Company manages the capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. In order to maintain or adjust the capital structure, the Company may issue new shares, sell assets, reduce debt or increase its debt. The capital of the Company comprises the shareholders' equity. The Company is not subject to any externally imposed capital requirements.

#### Classification of financial instruments

#### Fair Values and Classification

The Company's financial instruments consist of cash and cash equivalents, investment in convertible notes, investments in equity securities, accounts payable and convertible notes. Financial instruments are classified into one of the following categories: FVTPL, FVTOCI, or amortized cost. The carrying values of the Company's financial instruments are classified into the following categories:

| Financial Instrument            | Category       |
|---------------------------------|----------------|
| Cash                            | FVTPL          |
| Investment in convertible notes | FVTPL          |
| Investments                     | FVTPL          |
| Accounts payable                | Amortized cost |

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#### ADDITIONAL INFORMATION

#### **Off-Balance Sheet Arrangements**

As at November 30, 2021 and up to the current date, Entheon had no off-balance sheet arrangements.

#### Legal Proceedings

As at the date hereof, management was not aware of any legal proceedings involving Entheon.

#### **Contingent Liabilities**

As at November 30, 2021 and up to the current date management was not aware of any outstanding contingent liabilities relating to Entheon's activities.

#### **RISK FACTORS**

In addition to the risks described herein, reference is made to the section entitled "Risk Factors" in the Listing Statement, which is incorporated herein by reference. The risks described herein are not the only risks faced by Entheon and security holders of Entheon. Additional risks and uncertainties not currently known to Entheon, or that Entheon currently deems immaterial, may also materially and adversely affect its business. The business, financial condition, revenues or profitability of Entheon could be materially adversely affected by any of the risks set forth in this MD&A, in the documents incorporated by reference or such other risks. 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. Entheon'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 Entheon 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 the documents incorporated by reference herein, as all risk factors are important and should be carefully considered by a potential investor.

#### Limited operating history

The business of Entheon began in June 2019 and has yet to generate any significant revenue. Entheon is therefore subject to many of the risks common to early-stage enterprises, including undercapitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. There is no assurance that Entheon will ever be able to generate significant revenue or will be successful in achieving a return on shareholders' investment. Entheon's ultimate success will depend on its operating ability and ability to generate cash flow from sales of HaluGen's Psychedelics Genetic Test, and sales of Entheon's DMT Products and DMT Solutions to be developed and sold in the future. Investors should consider Entheon's likelihood of success in light of the early stage of operations.

#### Risks related to adverse and uncontrollable clinical results

Entheon is developing the DMT Products to treat patients who have substance use disorders and any unfavourable or adverse effects that may occur in its clinical trials could negatively impact the business

Fiscal year ended November 30, 2021

of Entheon even if such adverse effects are not shown to be related to Entheon's DMT Products. It is Entheon's intention to continue to develop the DMT Products focused on substance use disorders and addiction. Patients suffering from these disorders may be extremely sick and may have a high likelihood of experiencing adverse outcomes, including death, as a result of their disorder or due to other significant risks including relapse of their underlying addictions.

As a result, it is possible that Entheon will observe severe adverse outcomes during its clinical trials, including patient death, unrelated to Entheon's DMT Products and DMT Protocol. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to one of Entheon's DMT Products, its ability to obtain regulatory approval and/or achieve commercial acceptance for the related drug may be adversely impacted and its business could be materially harmed. In addition, other setbacks may occur which would require Entheon to conduct additional preclinical studies both invitro and invivo and/or additional clinical trials.

# Entheon will require substantial additional funding, which may not be available to it on acceptable terms, or at all, and, if not so available, may require Entheon to delay, limit, reduce or cease its operations

Entheon has used the proceeds from its previous equity offerings, and Entheon intends to use the proceeds from any possible future offerings, to, among other uses, advance its portfolio of DMT Products through preclinical and clinical development, engaging scientific and clinical advisors, filing patent applications, establishing key relationships, and conducting further research. Developing pharmaceutical solutions, including conducting preclinical studies both in vitro and in vivo and clinical trials, is expensive. Entheon will require substantial additional future capital in order to complete clinical development and commercialize its DMT Solutions.

Entheon will continue to require substantial additional capital to continue its clinical development and commercialization activities. Because successful development of its DMT Solutions is uncertain, Entheon is unable to estimate the actual amount of funding it will require to complete research and development and commercialize its products under development.

The amount and timing of Entheon's future funding requirements will depend on many factors, including but not limited to:

- whether its plan for clinical trials will be completed on a timely basis and, if completed, whether Entheon will be able to publicly announce results from its clinical trials in accordance with its announced milestones;
- whether Entheon is successful in obtaining the benefits of Health Canada's, EMA's and FDA's expedited development and review programs related to its DMT Products;
- whether Entheon is successful in obtaining interest for possible co-development and licensing out partners;
- the progress, costs, results of and timing of its clinical trials and also of its preclinical studies;
- the outcome, costs and timing of seeking and obtaining Health Canada, EMA, FDA and any other regulatory approvals;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of its DMT Products;
- its ability to maintain, expand and enforce the scope of its intellectual property portfolio, including the amount and timing of any payments Entheon may be required to make, or that it

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may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- its need and ability to hire additional management and scientific and medical personnel;
- the effect of competing psychedelic therapeutic products;
- its need to implement additional internal systems and infrastructure, including financial and reporting systems;
- as applicable, research grant terms that change over time or whose terms Entheon is unable to meet;
- its ability to attract and retain competent staff;
- changes in the political and economic environment in the jurisdictions in which Entheon operates, including adverse economic circumstances beyond COVID-19;
- the duration and effects of COVID-19 on Entheon's personnel, business, operations and financial condition;
- the duration and effects of COVID-19 on the personnel, business, operations and financial condition of Entheon's research partners and suppliers;
- unforeseen safety hazards associated with the DMT Products Entheon develops; and
- the economic and other terms, timing of and success of any collaboration, licensing or other transactions into which Entheon may enter in the future.

Some of these factors are outside of Entheon's control. Entheon does not believe that its existing capital resources are sufficient to enable Entheon to complete the development and commercialization of its DMT Solutions. Accordingly, Entheon expects that it will need to raise additional funds in the future.

Entheon may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution transactions and other collaborations, strategic alliances and licensing transactions. Additional funding may not be available to Entheon on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of Entheon securityholders. In addition, the issuance of additional Entheon Shares, or the possibility of such issuance, may cause the market price of the Entheon Shares to decline. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities.

If Entheon is unable to obtain funding on a timely basis, it may be required to significantly curtail one or more of its research or development programs and/or incur financial penalties. Entheon also could be required to seek funds through transactions with collaborative partners or otherwise that may require Entheon to relinquish rights to some of its technologies or psychedelic therapeutic products or otherwise agree to terms unfavourable to Entheon.

#### Possible increase in costs beyond what is currently expected as a result of regulatory review

If Health Canada, the FDA, or the EMA requires that Entheon perform additional nonclinical studies or clinical trials, or if Entheon determines that additional clinical trials are required for its DMT Products, its expenses would further increase beyond what is currently expected and the anticipated timing of any potential approval of its DMT Products or licensing out agreement would likely be delayed. Further, there can be no assurance that the costs Entheon will need to incur to obtain regulatory approval of its DMT Products.

Eisaal yoor onded Nevember 20, 2021

## Fiscal year ended November 30, 2021

# Entheon has a limited operating history and expects a number of factors to cause its operating results to fluctuate on an annual basis, which may make it difficult to predict the future performance of Entheon

Entheon is a research and development biomedical company with a limited operating history. Entheon's operations to date have been focused on developing its Dosing Strategies, conducting inhouse research, preparing proprietary dose forms of psychedelic molecules into an FDA, EMA and Health Canada approval model for eventual development of authorized Dosing Strategies for future use in clinical trials, developing clinical trials protocols, filing patent applications and establishing key relationships. Entheon has yet to commence clinical trials for the psychedelic therapeutic products in its pipeline and has yet to receive approvals from regulatory agencies.

Consequently, any predictions made about Entheon's future success or viability may not be as accurate as they could be if Entheon had a longer operating history or approved products on the market. Entheon's operating results are expected to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond its control. Factors relating to Entheon's business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of its DMT Products in clinical development, including its ability to receive approval from Health Canada, the FDA or the EMA for its Dosing Strategies in clinical trials;
- delays in the commencement, enrolment and timing of preclinical and clinical trials;
- difficulties in identifying patients suffering from its target indications;
- the success of its clinical trials through all phases of clinical development;
- potential side effects of its DMT Products that could delay or prevent approval or license-out agreements or cause approved solutions to be taken off the market;
- its ability to obtain additional funding to develop its DMT Solutions;
- its ability to attract and retain talented and experienced people;
- competition from existing products or new products that continue to emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for its products;
- its ability to adhere to clinical trial requirements directly or with third parties such as CROs;
- its dependency on third-party manufacturers to manufacture products and key ingredients;
- its ability to establish or maintain collaborations, licensing or other transactions;
- its ability to defend against any challenges to its intellectual property including, claims of patent infringement;
- its ability to enforce its intellectual property rights against potential competitors;
- its ability to secure additional intellectual property protection for its developing DMT Solutions and associated technologies;
- its ability to attract and retain key personnel to manage its business effectively;
- a biological or chemical effect that Entheon does not predict;
- adverse economic circumstances;
- potential liability claims; and
- the duration and effects of COVID-19 on Entheon's personnel, business, operations and financial condition.

Accordingly, the results of any historical quarterly or annual periods should not be relied upon as indications of future operating performance.

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Entheon is preparing to conduct important preclinical and clinical trials in Europe. The risks associated with conducting research and clinical trials abroad could materially adversely affect Entheon's business. Currently, clinical trials are planned at the Centre for Human Drug Research in Leiden, the Netherlands. Additional sites in Europe and elsewhere are currently being evaluated for preclinical trials and subsequent studies.

#### Risks of operating in European countries

Entheon is subject to additional risks related to operating in countries in Europe including:

- differing regulatory requirements in Europe;
- unexpected changes in price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of collecting and shipping patient material;
- import and export requirements and restrictions;
- compliance with tax, employment, immigration and labour laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- potential liability under the Corruption of Foreign Public Officials Act or comparable foreign regulations;
- 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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

# Entheon has never been profitable, it has only one product approved for commercial sale, and to date it has not generated any significant revenue. As a result, Entheon's ability to reduce its losses and reach profitability is unproven, and thus, Entheon may never achieve or sustain profitability.

Entheon has never been profitable and does not expect to be profitable in the foreseeable future. On April 5, 2021, Entheon, through its wholly-owned subsidiary HaluGen, launched its Psychedelics Genetic Test for sale on HaluGen's online platform and has only begun generating revenue form this product. Entheon has not yet submitted any psychedelic therapeutic solutions for approval by regulatory authorities in Canada, the European Union, the United States or elsewhere.

To date, Entheon has devoted most of its financial resources to research and development, including drug discovery research, preclinical development activities and clinical trial preparation, as well as corporate overhead. Entheon has not generated any significant revenues from product sales. Entheon expects to continue to incur losses for the foreseeable future, and expects these losses to increase as Entheon continues its development of, and seek regulatory approvals for its DMT Solutions, prepare

Fiscal year ended November 30, 2021

for and begin the commercialization of any approved solutions and add infrastructure and personnel to support its continuing product development efforts. Entheon anticipates that any such losses could be significant for the next several years. If its DMT Products fail in clinical trials or do not gain regulatory approval, or if its DMT Solutions do not achieve market acceptance, Entheon may never become profitable. As a result of the foregoing, Entheon expects to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on Entheon's stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical solution development, Entheon is unable to accurately predict the timing or amount of increased expenses or when, or if, Entheon will be able to achieve profitability. In addition, Entheon's expenses could increase if it is required by Health Canada, the FDA or the EMA to perform studies or trials in addition to those currently expected, or if there are any delays in completing its clinical trials or the development of any of its DMT Solutions. The amount of future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenues.

# There are limited suppliers for API used in Entheon's DMT Products. Problems with the third parties that manufacture the API used in its DMT Products may delay its clinical trials or subject Entheon to liability

Entheon does not currently own or operate manufacturing facilities for clinical or commercial production of the API used in any of Entheon's DMT Products. Entheon has no experience in API manufacturing, and it lacks the resources and the capability to manufacture any of the APIs used in its DMT Products, on either a clinical or commercial scale. As a result, Entheon relies on third parties to supply the API used in each of its DMT Products. Entheon expects to continue to depend on third parties to supply the API for its current and future solution candidates and to supply the API in commercial quantities, in the foreseeable future. Entheon is ultimately responsible for confirming that the APIs used in its DMT Products are manufactured in accordance with applicable regulations.

Entheon's third-party suppliers may not carry out their contractual obligations or meet its deadlines. In addition, the API they supply to Entheon may not meet its specifications and quality policies and procedures or they may not be able to supply the API in commercial quantities. If Entheon needs to find alternative suppliers of the API used in any of its DMT Products, it may not be able to contract for such supplies on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers would have an adverse effect on Entheon's ability to continue clinical development of its DMT Products or commercialization of its DMT Solutions.

If its third-party drug suppliers fail to achieve and maintain high manufacturing standards in compliance with current good manufacturing practices regulations, Entheon could be subject to certain product liability claims in the event such failure to comply resulted in defective products that caused injury or harm.

# Entheon cannot be certain that any of its DMT Products will receive regulatory approval, and without regulatory approval Entheon will not be able to market such solutions

Entheon's business currently depends on the successful development and commercialization of its DMT Solutions. As discussed in further detail under the heading "Description of the Business – Regulations" Entheon anticipates that DMT will be subject to extensive and rigorous regulation by

Fiscal year ended November 30, 2021

Health Canada, the FDA and the EMA. Health Canada, the FDA and the EMA regulate the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical products in Canada, the United States and the European Union respectively, to ensure that such medical products distributed are safe and effective for their intended use. Entheon's ability to generate revenue related to solution sales, if ever, will depend on the successful development and regulatory approval of its DMT Solutions. Entheon could fail to receive regulatory approval for its DMT for many reasons, including but not limited to:

- disagreement with the design or implementation of its clinical trials;
- failure to demonstrate that a 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 product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with Entheon's interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of Entheon's product candidates to support the submission and filing of a submission to obtain regulatory approval;
- deficiencies in the manufacturing processes or the failure of facilities of collaborators with whom Entheon contracts for clinical and commercial supplies to pass a pre-approval inspection; or
- changes in the approval policies or regulations that render Entheon's preclinical and clinical data insufficient for approval.

The process of getting regulatory approval is both time consuming and costly and Entheon's ability to satisfactorily navigate this process will have a material impact on its business and prospects. Additionally, the receipt of regulatory approval may be impacted by the delays, risks, and related costs implications discussed under the heading "General Development of the Business – Business Outlook for the Upcoming Year" and there is no certainty that Entheon will ever receive regulatory approval. If Entheon does obtain such approvals, Entheon will continue to be subject to ongoing compliance and reporting requirements. Failure to comply with the requirements would have a material adverse impact on the business, financial condition and operating results of Entheon. Entheon cannot predict the time required to secure all appropriate regulatory approvals for its protocols, or the extent of testing and documentation that may be required by governmental authorities. Any delays in obtaining, or failure to obtain the necessary regulatory approvals will significantly delay the development of Entheon's protocols and could have a material adverse effect on the business, results of operations and financial condition of Entheon. Additionally, to the extent any further approvals, permits or licenses are required and not obtained, Entheon may be prevented from operating and/or expanding its business, which could have a material adverse effect on Entheon's business, financial condition and results of operations. If Entheon is unable to obtain approval from Health Canada, the FDA, the EMA, or other regulatory agencies, for any of its DMT Products, or if, subsequent to approval as applicable, Entheon is unable to successfully commercialize its DMT Solutions, it will not be able to generate sufficient revenue to become profitable or to continue its operations.

# Delays in the commencement, enrolment and completion of clinical trials could result in increased costs to Entheon and delay or limit Entheon's ability to obtain regulatory approval for any of its DMT Products

Delays in the commencement, enrolment and completion of preclinical and clinical trials could increase Entheon's product development costs or limit the regulatory approval of its DMT Products. Entheon does not know whether any future trials or studies of its other psychedelic therapeutic products will

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begin on time or will be completed on schedule, if at all. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, including delays or shortages in available product, required clinical trial administrative actions, slower than anticipated patient enrolment, changing standards of care, availability or prevalence of use of a comparative product or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrolment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new solution can require the enrolment of a sufficient number of patients, including patients who are suffering from the disorder the solution is intended to treat and who meet other eligibility criteria. Rates of patient enrolment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, that include the age and condition of the patients and the stage and severity of disorder, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and/or availability of investigational treatment options for the relevant disorder. Additionally, delays in the commencement, enrolment and completion of preclinical and clinical trials could result from the duration and impact of COVID-19.

A psychedelic therapeutic solution can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for psychedelic therapeutic products is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a psychedelic therapeutic solution may not predict the results that will be obtained in later phase clinical trials of the psychedelic therapeutic solution. Health Canada, the EMA, the FDA or other applicable regulatory authorities may suspend clinical trials of a psychedelic therapeutic solution at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. Entheon may not have the financial resources to continue development of, or to enter into collaborations for, a psychedelic therapeutic solution if Entheon experiences any problems or other unforeseen events that delay or prevent regulatory approval of, or its ability to commercialize, psychedelic therapeutic products, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to recruit and retain qualified personnel;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- negative or inconclusive results from its clinical trials or the clinical trials of others for psychedelic therapeutic products similar to its, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected drug-related side effects experienced by subjects in its clinical trials or by individuals using drugs similar to its DMT Products;
- conditions imposed by the EMA, Health Canada, the FDA or comparable foreign authorities regarding the scope or design of its clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates and high fail rates of research subjects;
- inadequate supply or quality of psychedelic therapeutic solution components or materials or other supplies necessary for the conduct of its clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of its DMT Products during clinical trials; or
- unfavourable Health Canada, EU, FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

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# Entheon has minimal sales, marketing or distribution experience and it will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing transactions

Entheon has minimal sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, Entheon will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that its DMT Solutions will be approved by Health Canada, the FDA or the EMA. For psychedelic therapeutic products where Entheon decides to perform sales, marketing and distribution functions itself or through third parties, it could face a number of additional risks, including that Entheon or its third-party sales collaborators may not be able to build and maintain an effective marketing or sales force. If Entheon uses third parties to market and sell its solutions, it may have limited or no control over their sales, marketing and distribution activities on which its future revenues may depend.

# Entheon may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect its ability to develop its DMT Solutions and its financial condition and operating results

Because developing psychedelic therapeutic products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved solutions are expensive, Entheon may seek to enter into collaborations with companies that have more experience. Additionally, if any of its DMT Solutions receives marketing approval, Entheon may enter into licensing out agreements or sales and marketing transactions with third parties with respect to its unlicensed territories. If Entheon is unable to enter into transactions on acceptable terms, if at all, it may be unable to effectively market and sell its solutions in its target markets. Entheon expects to face competition in seeking appropriate collaborators. Moreover, collaboration transactions are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. Entheon may not be successful in its efforts to establish and implement collaborations or other alternative transactions for the development of its DMT Solutions.

When Entheon collaborates with a third party for development and commercialization of a psychedelic therapeutic solution or collaboration in making grant applications, it can expect to relinquish some or all of the control over the future success of that psychedelic therapeutic solution to the third party. One or more of its collaboration partners may not devote sufficient resources to the commercialization of its DMT Solutions or may otherwise fail in their commercialization. The terms of any collaboration or other transaction that Entheon establishes may contain provisions that are not favourable to Entheon. In addition, any collaboration that Entheon enters into may be unsuccessful in the development and commercialization of its DMT Solutions. In some cases, Entheon may be responsible for continuing preclinical and initial clinical development of a psychedelic therapeutic solution or research program under a collaboration transaction, and the payment Entheon receives from its collaboration partner may be insufficient to cover the cost of this development. If Entheon is unable to reach agreements with suitable collaborators for its DMT Solutions, it would face increased costs, it may be forced to limit the number of its DMT Solutions it can commercially develop or the territories in which it can market them. As a result, Entheon might fail to commercialize solutions for which a suitable collaborator cannot be found. If Entheon fail to achieve successful collaborations, its operating results and financial condition could be materially and adversely affected.

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#### Protection and enforcement of Entheon's intellectual property in all jurisdictions it operates in

Entheon's success will depend in part upon its ability to protect Entheon's intellectual property interests in Canada, the United States and Europe and upon the nature and scope of the intellectual property protection it receives. The ability to compete effectively and to achieve partnerships will depend on Entheon's ability to develop and maintain proprietary aspects of Entheon's DMT Solutions and to operate without infringing on the proprietary rights of others. As described in further detail under the heading "Description of the Business – Intangible Properties – Patents", Entheon has filed four provisional patent applications with the United States Patent and Trademark Office. The United States Patent and Trademark Office might not approve the patent applications or might delay approval for a number of reasons, including as a result of the on-going COVID-19 pandemic. Additionally, there is no assurance that Entheon's pending patent applications will be approved in a form that will be sufficient to protect its intellectual property interests in Canada, the United States and Europe. As a result, Entheon could experience delays in its ability to distribute and commercialize its DMT Solutions, which would have a material adverse effect on Entheon's business, results of operations and financial condition.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Patents issued to Entheon may be challenged, invalidated or circumvented. To the extent Entheon's intellectual property, including licensed intellectual property, offers inadequate protection in any of the jurisdictions in which it intends to operate in, or is found to be invalid or unenforceable, Entheon is exposed to a greater risk of direct competition. If Entheon's intellectual property does not provide adequate protection against its competitors' products, Entheon's competitive position could be adversely affected, as could its business, financial condition and results of operations. Both the patent application process and the process of managing patent disputes can be time consuming and expensive, and the laws of some foreign countries may not protect Entheon's intellectual property rights to the same extent as do the laws of Canada and the United States. Entheon will be able to protect the its intellectual property from unauthorized use by third parties only to the extent that the its intellectual property interests, key products, and any future products are covered by valid and enforceable intellectual property rights in each jurisdiction in which it operates in.

# Entheon may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights

Entheon may from time to time seek to enforce its intellectual property rights against infringers when it determines that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If Entheon chooses to enforce its patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of its patents and the patents it has licensed may be challenged if a petition for post grant proceedings such as inter-partes review and post grant review is filed within the statutorily applicable time with the Canadian Intellectual Property Office, the United States Patent and Trademark Office or the European Patent Office. These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if Entheon were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that Entheon does not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such

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patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe its intellectual property rights.

# If Entheon is not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of its psychedelic therapeutic products could be significantly diminished

Entheon relies on trade secrets to protect its proprietary information, especially where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Entheon relies in part on confidentiality agreements with its employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect its trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover its trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of its proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect its competitive business position.

# Entheon will need to expand its operations and increase the size of its company, and it may experience difficulties in managing growth

As of the date hereof, Entheon has 4 full-time employees and 20 consultants and part-time contractors. As Entheon advances its DMT Products through preclinical studies and clinical trials, Entheon will need to increase its product development, scientific and administrative headcount to manage these programs. In addition, to meet its obligations as a public company, Entheon may need to increase its general and administrative capabilities. Entheon's management, personnel and systems currently in place may not be adequate to support this future growth. If Entheon is unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

#### Changes is legislation, regulations and guidelines

Entheon's operations are subject to various laws, regulations and guidelines relating to, among other things, drug research, development, marketing practices, health and safety, the conduct of operations and clinical trials. In addition to Health Canada, EMA and FDA restrictions on the marketing of pharmaceutical solutions, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical industries in recent years, as well as consulting or other service agreements with physicians or other potential referral sources. While to the knowledge of management, Entheon is currently in compliance with all such laws, changes to applicable laws, regulations and guidelines may cause adverse effects to its operations. The risks to the business of Entheon represented by this or similar risks are that they could significantly reduce the addressable market for Entheon's solutions and could materially and adversely affect the business, financial condition and results of its operations.

#### Psychedelic regulatory risks

Successful execution of the Company's strategy is contingent, in part, upon compliance with regulatory requirements from time to time enacted by governmental authorities and obtaining all regulatory approvals, where necessary, for the sale of psychedelic therapeutic products. The psychedelic therapy

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industry is a new and emerging industry with ambiguous existing regulations and uncertainty as to future regulations; 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 its 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 Company will incur ongoing costs and obligations related to regulatory compliance. Failure to comply with regulations may result in additional costs for corrective measures, penalties or result in restrictions on the Company's operations. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Company's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, financial condition and operating results of the Company.

#### Third party risk with respect to preclinical studies and clinical trials

Entheon will rely on foreign contract research organizations, including CHDR, to conduct its preclinical and clinical development activities. Preclinical activities include toxicological and pharmacological assays as well as in vivo studies using specific disease models. Clinical development activities include trial design, regulatory submissions, patient recruitment, trial monitoring, data management and analysis, and safety monitoring. If there is any dispute or disruption in Entheon's relations with CHDR or other third parties, Entheon's active development programs will face delays. Although Entheon does not anticipate any risk specific to CHDR's foreign jurisdiction (being the Netherlands), if they or other third parties fail to perform as expected or if their work fails to meet regulatory requirements, Entheon's testing could be delayed, cancelled or rendered ineffective.

#### Reliance on third party contract manufacturers

Entheon will rely on contract manufacturing organizations ("**CMOs**") to develop and manufacture its DMT Products, over which it has limited control. Entheon intends to rely on CMOs for manufacturing, filling, packaging, storing and shipping of drug products in compliance with local GMP regulations applicable to its DMT Products. All applicable jurisdictions, including Health Canada, EMA and FDA, ensure the quality of drug products by carefully monitoring drug manufacturers' compliance with GMP regulations. The GMP 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 Entheon's timetable and requirements. If Entheon is unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, it may be delayed in the development of its product candidates. Further, CMOs must operate in compliance with GMP and failure to do so could result in, among other things, the disruption of product supplies. Entheon's dependence upon third parties for the manufacture of Entheon's products may adversely affect profit margins and Entheon's ability to develop and deliver products on a timely and competitive basis.

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#### Safety and efficacy risks

Before obtaining marketing approval from regulatory authorities for the sale of Entheon's DMT Products, Entheon must conduct extensive clinical trials in humans to demonstrate the safety and efficacy. Clinical testing is difficult to design and implement, can take many years to complete and can have uncertain outcomes. The outcome of early studies 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, despite promising results in earlier trials. Entheon does not know whether the clinical trials it conducts will demonstrate adequate efficacy and safety to result in the receipt of market authorization of Entheon's DMT Products in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk faced by Entheon is the possibility that none of Entheon's product candidates will successfully gain market approval from regulatory authorities, resulting in Entheon's inability to derive any commercial revenue from them after investing significant amounts of capital in their development.

# Entheon may not be able to manage its business effectively if it is unable to attract and retain key personnel and consultants

Entheon may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If Entheon is not able to attract and retain necessary personnel and consultants to accomplish its business objectives, it may experience constraints that will significantly impede the achievement of its development objectives, its ability to raise additional capital and its ability to implement its business strategy.

Entheon is highly dependent on the development, regulatory, commercialization and business development expertise of its management team, key advisors and consultants. If Entheon loses one or more of its executive officers or key advisors or consultants, its ability to implement its business strategy successfully could be seriously harmed. Any of its executive officers or key advisors or consultants may terminate their engagement at any time. Replacing executive officers, key advisors and consultants may be difficult and may take an extended period of time because of the limited number of individuals in Entheon's industry. Competition to hire and retain employees and consultants from this limited pool is intense, and Entheon may be unable to hire, train, retain or motivate these additional key personnel and consultants. Entheon's failure to retain key personnel or consultants could materially harm its business.

In addition, Entheon has scientific and clinical advisors and consultants who assist Entheon in formulating its research, development and clinical strategies. These advisors are not its employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to Entheon. Although Entheon's current scientific and clinical advisors have entered into non-compete agreements which apply during the course of engagement and within the 12 months following the termination of the engagement, future advisors may not. If a conflict of interest arises between their work for Entheon and their work for another entity, Entheon may lose their services. In addition, future advisors may have transactions with other companies to assist those companies in developing products or technologies that may compete with those of Entheon.

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#### Insurance and uninsured risks

Entheon's business is subject to a number of risks and hazards generally, including adverse clinical trial results, accidents, labour disputes and changes in the regulatory environment. Such occurrences could result in damage to assets, personal injury or death, environmental damage, delays in operations, monetary losses and possible legal liability.

Entheon's insurance will not cover all the potential risks associated with its operations. Entheon may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not be available or may not be adequate to cover any resulting liability. Moreover, insurance against risks such as environmental pollution or other hazards encountered in the operations of Entheon is not generally available on acceptable terms. Entheon might also become subject to liability for pollution or other hazards which may not be insured against or which Entheon may elect not to insure against because of premium costs or other reasons. Losses from these events or any significant uninsured liability may require Entheon to pay substantial amounts, which would adversely affect its financial position and results of operations.

# Entheon may be materially adversely affected in the event of cyber-based attacks, network security breaches, service interruptions, or data corruption

Entheon relies on information technology to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities. Entheon uses technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Entheon's information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Although Entheon has developed systems and processes that are designed to protect proprietary or confidential information and prevent data loss and other security breaches, such measures cannot provide absolute security. If its systems are breached or suffer severe damage, disruption or shutdown and Entheon is unable to effectively resolve the issues in a timely manner, its business and operating results may significantly suffer and it may be subject to litigation, government enforcement actions or potential liability. Security breaches could also cause Entheon to incur significant remediation costs. result in product development delays, disrupt key business operations, including development of its DMT Solutions, and divert attention of management and key information technology resources.

#### Internal controls

Effective internal controls are necessary for Entheon to provide reliable financial reports and to help prevent fraud. Although Entheon will undertake a number of procedures and will implement a number of safeguards, in each case, in order to help ensure the reliability of its financial reports, including those imposed on Entheon under Canadian securities law, Entheon cannot be certain that such measures will ensure that Entheon will maintain adequate control over financial processes and reporting. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm Entheon's results of operations or cause it to fail to meet its reporting obligations. If Entheon or its auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could reduce the market's confidence in Entheon's consolidated financial statements and materially adversely affect the trading price of the Entheon Shares.

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Management of Entheon will ensure the accounting cycle, payroll administration, operational activities, and financial reporting controls to assess internal control risks and to ensure proper internal control is in place. One of the deficiencies in internal control is the lack of segregation of accounting duties due to the limited size of Entheon. However, the threat of this deficiency is considered immaterial as management has taken effective measures to mitigate this weakness.

The potential risk that flows from the identified deficiencies and weaknesses is the risk of potential fraud. However, the risk of fraud is considered low as management anticipates taking a number of measures as stated above to mitigate the potential risk of fraud, including without limitation: (i) all purchase and payment, including payroll, must be authorized by management; (ii) all capital expenditures must be preapproved by the Board; (iii) all source documents in any other language other than English must be translated and scanned for accounting entries and recordkeeping purposes; (iv) and almost all of Entheon's cash will be deposited with a Canadian bank in Vancouver, Canada. Bank statements of Entheon will be reviewed by the CFO of Entheon regularly.

The Board will continue to monitor the operations of Entheon, evaluate the internal controls, and develop measures in the future to mitigate any potential risks and weaknesses.

#### Litigation

Entheon may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which Entheon becomes involved be determined against Entheon such a decision could adversely affect Entheon's ability to continue operating and the market price for the Entheon Shares and could use significant resources. Even if Entheon is involved in litigation and wins, litigation can redirect significant company resources.

#### Conflicts of interest

Certain of the directors and officers of Entheon are engaged in, and will continue to engage in, other business activities on their own behalf and on behalf of other companies and, as a result of these and other activities, such directors and officers of Entheon may become subject to conflicts of interest. The CBCA provides that in the event that a director or senior officer has a material interest in a transaction or agreement or proposed transaction or agreement that is material to an issuer, the director or senior officer must disclose his interest in such contract or agreement and a director must refrain from voting on any matter in respect of such contract or agreement, subject to and in accordance with the CBCA. To the extent that conflicts of interest arise, such conflicts will be resolved in accordance with the provisions of the CBCA. To the management of Entheon's knowledge, as at the date hereof there are no existing conflicts of interest between Entheon and a director or officer of Entheon except as otherwise disclosed in the Listing Statement.

#### Impact of COVID-19

Entheon's business, operations and financial condition could be materially and adversely affected by the outbreak of epidemics or pandemics or other health crises, including the recent outbreak of COVID-19. On January 30, 2020, the World Health Organization declared the outbreak of a global health emergency and on March 13, 2020 the United States declared that the COVID-19 outbreak in the United States constitutes a national emergency. To date, there have been a large number of temporary business closures, quarantines and a general reduction in consumer activity in Canada, the United States, Europe and China. The outbreak has caused companies and various international

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jurisdictions to impose travel, gathering and other public health restrictions. While these effects are expected to be temporary, the duration of the various disruptions to businesses locally and internationally and the related financial impact cannot be reasonably estimated at this time. Similarly, Entheon cannot estimate whether or to what extent this outbreak and the potential financial impact may extend to countries outside of those currently impacted. Entheon is actively assessing and responding where possible to the potential impact of the COVID-19 pandemic. Entheon may face disruption to restrictions on operations, delays and uncertainties to planned clinical trials, travel restrictions, impact on personnel and the impact on the economic activity in affected countries or regions can be expected and can be difficult to quantify. Such pandemics or diseases represent a serious threat to maintaining a skilled workforce industry and could be a major health care challenge for Entheon. There can be no assurance that Entheon's personnel will not be impacted by this pandemic and ultimately that Entheon would see its workforce productivity reduced or incur increased medical costs/insurance premiums as a result of these health risks. In addition, the COVID-19 pandemic has created a dramatic slowdown in the global economy. Depending on the length and severity of the pandemic, COVID-19 could impact Entheon's operations, could cause delays relating to pre-clinical and clinical trials and receipt of approval from Health Canada, the FDA and/or the EMA, could postpone research activities, and could impair Entheon's ability to raise funds depending on COVID-19's effect on capital markets. The duration of the COVID-19 pandemic outbreak and the resultant travel restrictions, social distancing, government response actions, business closures and business disruptions, can all have an impact on Entheon's operations and access to capital. There can be no assurance that Entheon will not be impacted by adverse consequences that may be brought about by the COVID-19 pandemic on global financial markets, share prices and financial liquidity and thereby that may severely limit the financing capital available. Finally, 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 Entheon in future periods.

#### Psychedelic Regulatory Risks and Risks of Violations of Law

Psychedelic therapy is a new and emerging industry with ambiguous existing regulations and uncertainty as to future regulations. Certain psychedelics may be illegal substances other than when used for scientific or medical purposes. As such, new risks may emerge, and management may not be able to predict all such risks or be able to predict how such risks may result in actual results differing from the results contained in any forward-looking statements. This industry is subject to extensive controls and regulations, which may significantly affect the financial condition of market participants. The marketability of any product may be affected by numerous factors that are beyond the control of the Company and cannot be predicted, such as changes to government regulations, including those relating to taxes and other government levies which may be imposed. Changes in government levies, including taxes, could reduce Entheon's earnings and could make future capital investments or operations uneconomic. The psychedelic therapy industry is also subject to numerous legal challenges, which may significantly affect the financial condition of market participants and which cannot be reliably predicted.

Some of the Company's planned business activities, while believed to be compliant with applicable laws in the jurisdictions in which the Company operates, may be illegal or become illegal in such jurisdictions. If the Company's historical current or future operations were found to be in violations of any such laws the Company may be subject to enforcement actions in such jurisdictions including but not limited to penalties, including criminal and significant civil monetary penalties, damages, fines,

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imprisonment, exclusion from participation in government programs, injunctions, or refusal to allow the Company to enter into certain contracts, any of which could adversely affect the Company's ability to operate its business and its results of operation.

Local, provincial and federal laws and regulations governing psychedelics are broad in scope and subject to evolving interpretations, which could require the Company to incur substantial costs associated with bringing the Company's operations into compliance. In additional, violation of these laws or allegations of such violations could disrupt the Company's operations and result in a material adverse effect on its financial performance. It is beyond the Company's scope to predict the nature of any future change to existing laws, regulations, policies, interpretations or applications, nor can the Company determine what effects such changes, when and if promulgated, could have on the Company's business.