**ANNUAL INFORMATION FORM**


**ENTHEON BIOMEDICAL CORP.**

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For the year ended November 30, 2020

Dated June 24, 2021

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## EXPLANATORY NOTES AND CAUTIONARY STATEMENTS

In this annual information form (this "**AIF**" or "**Annual Information Form**"), unless the context otherwise requires, the "**Company**" or "**Entheon**" refers to Entheon Biomedical Corp. This AIF applies to the business activities and operations of the Company for the financial year ended November 30, 2020. Unless otherwise indicated, the information in this AIF is given as of June 24, 2021.

This AIF contains company names, product names, trade names, trademarks and service marks of the Company and other organizations, all of which are the property of their respective owners.

This AIF contains references to Canadian dollars and United States dollars. References in this AIF to "Cdn$" are to Canadian dollars. References in this AIF to "USD$" are to US dollars. References in this AIF to "€" are to Euros. References in this AIF to "GBP£" are UK pounds sterling. Any references to "$" not preceded by "Cdn" or "US" are to Canadian dollars. On June 24, 2021, the closing exchange rate for US dollars to Canadian dollars, as quoted by the Bank of Canada was USD$1.00:CAD$1.2316 (CAD$1.00:USD$0.8120). On June 24, 2021, the closing exchange rate for Euros to Canadian dollars, as quoted by the Bank of Canada was €1:00:CAD$1.4699 (CAD$1.00:€0.6803). On June 24, 2021, the closing exchange rate for UK pounds sterling to Canadian dollars, as quoted by the Bank of Canada was GBP£1.00:CAD$1.7141 (CAD$1.00: GBP£0.5834).

### *Cautionary Statement Regarding Forward-Looking Information*

This AIF and the Company's other public disclosure contain "forward-looking information" within the meaning of applicable Canadian securities laws ("**forward-looking information**") concerning the Company's business plans, including, but not limited to, anticipated results and developments in the Company's operations in future periods and other matters that may occur in the future. In certain cases, forward-looking information can be identified by the use of words such as "plans", "expects", "is expected", "budget", "target", "scheduled", "estimates", "forecasts", "intends", "anticipates", "determine", "continue", "projects", "potential", "proposed" or "believes", or variations or the negative of such words and phrases, or statements that certain actions, events or results "may", "could", "whether to", "would", "should", "likely", "might" or "will be taken", "occur" or "be achieved" or the negative of these terms or comparable terminology. Forward-looking information contained in this AIF includes, but is not limited to, statements regarding:

- the competitive and business strategies of the Company;
- market prices, values and other economic indicators;
- receipt and timing of governmental approvals, including Health Canada, FDA and EMA approvals;
- the performance of the Company's business and operations;
- the intention to grow the business, operations and potential activities of the Company;
- the competitive conditions of the industry;
- the anticipated changes to Canadian, United States and EU federal laws regarding the legalization of psychedelics and specifically DMT;
- whether the Company will continue to be in compliance with regulatory requirements;
- the Company's intention to build a brand and develop the DMT Solutions;

- the Company's intention to build valuable intellectual property and the anticipated benefits therefrom;
- analyses and other information based on expectations of future performance and planned products;
- possible events, conditions or financial performance that is based on assumptions about future economic conditions and courses of action;
- timing, costs and potential success of future activities on the Company's facilities and projects;
- future outlook and goals;
- Entheon's development of electroencephalograph monitoring in connection with its partnership with Divergence Neuro Technologies Inc., including anticipated uses, objectives, future plans, and estimated costs relating thereto;
- Entheon's development of virtual reality and augmented reality digital products, including anticipated uses, objectives, future plans, and estimated costs relating thereto;
- future investments of Entheon in Heading Health, LLC, anticipated results and benefits resulting therefrom, future plans of Heading Health, LLC and estimated costs relating thereto;
- the commercial expansion of HaluGen, the anticipated uses and benefits arising from the development of HaluGen's products and research, future plans of HaluGen and estimated costs relating thereto;
- closing of the Lobo Agreement (as defined herein), the anticipated uses and benefits arising from the development of Lobo's products and research, and future plans of Lobo;
- whether the Company will have sufficient working capital and its ability to raise additional financing required in order to develop its business and continue operations;
- effects of COVID-19; and
- planned expenditures and budgets and the execution thereof.

Forward-looking information is not a guarantee of future performance and is based upon a number of estimates and assumptions of management in light of management's experience and perception of trends, current conditions and expected developments, as well as other factors that management believes to be relevant and reasonable in the circumstances, including, without limitation, assumptions about:

- 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;
- general demand and consumer interest in the Company's products;
- competition;
- anticipated and unanticipated costs;
- the ability of the Company to obtain the necessary financing on acceptable terms;

- government regulation of the psychedelic-drug industry;
- the timely receipt of any required regulatory approvals;
- the ability of the Company to obtain qualified staff and clinical and scientific consulting services in a timely and cost-efficient manner;
- expectations regarding the level of disruption as a result of COVID-19; and
- the ability of the Company to conduct operations in a safe, efficient and effective manner.

While the Company considers these assumptions to be reasonable, the assumptions are inherently subject to significant business, social, economic, political, regulatory, competitive and other risks and uncertainties, contingencies and other factors that could cause actual actions, events, conditions, results, performance or achievements to be materially different from those projected in the forward-looking information. Many assumptions are based on factors and events that are not within the control of the Company and there is no assurance they will prove to be correct.

Furthermore, by their very nature, forward-looking information involves a variety of known and unknown risks, uncertainties and other factors which may cause the actual plans, intentions, events, results, performance or achievements of the Company to be materially different from those expressed or implied by such forward-looking information. Such risks, uncertainties and other factors include, without limitation, those related to:

- the industry-wide risks;
- fluctuations in capital markets and share prices;
- risks related to the ability to obtain financing needed to fund the continued development of the Company's business;
- the Company’s ability to manage anticipated and unanticipated costs;
- risks related to securing patients for the Company’s clinical trials and the outcome of such trials;
- risks related to securing and protecting the Company's intellectual property rights;
- risks related to the Company's failure to obtain necessary Health Canada, FDA, EMA and other regulatory approvals as scheduled or at all;
- risks related to the Company's inability to maintain or improve its competitive position;
- risks related to the Company's ability to establish its business internationally;
- risks related to the Company's failure to retain key personnel and hire additional personnel needed to develop its business;
- risks related to the Company's failure to adequately evaluate its current business and its future prospects;
- risks related to the Company's business practice reputation being negatively affected by unfavourable publicity or consumer perception of the psychedelic-drug industry;

- the impact of any negative scientific studies on the effects of DMT and other psychedelics;
- market conditions, volatility and global economic conditions;
- environmental risks;
- governmental regulations;
- restrictions imposed by the Canadian Securities Exchange and other regulatory authorities on the Company's business;
- risks related to foreign exchange rate fluctuations, as applicable;
- insurance and tax risks;
- general risks and uncertainties related to the Company's prospects and business strategy; and
- public health crises such as the COVID-19 pandemic, and any worsening thereof, having an adverse impact on the Company's business; and
- the risks described in the section of this AIF entitled *"Risk Factors"*;

This is not an exhaustive list of the risks and factors that may affect the Company's forward-looking information. Although the Company has attempted to identify important factors that could affect the Company and may cause actual actions, events, conditions, results, performance or achievements to differ materially from those described in the forward-looking information, there may be other factors that cause actions, events, conditions, results, performance or achievements not to be as anticipated, estimated or intended. In addition to those discussed in this AIF, please refer to the risks described in the Company's public disclosure record.

The Company cautions that the foregoing lists of important assumptions and factors are not exhaustive. Other events or circumstances could cause actual results to differ materially from those estimated or projected and expressed in, or implied by, the forward-looking information contained in this AIF. There can be no assurance that forward-looking information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such information. Accordingly, readers should not place undue reliance on forward-looking information. The Company does not undertake any obligation to publicly update or revise any forward-looking information other than as required under applicable securities laws.

## DEFINITIONS AND GLOSSARY OF TERMS

The following is a glossary of certain terms used in this AIF, including the summary that follows. Words importing the singular, where the context requires, include the plural and vice versa and words importing any gender include all genders. Certain additional terms are defined within the body of this AIF and in such cases will have the meanings ascribed thereto.

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| **AIF** | This Annual Information Form. |
| **Amalgamation** | Has the meaning ascribed thereto under the heading "*General Development of the Business - Events From March 31, 2020 to Fiscal Year Ended November 30, 2020*." |
| **BCBCA** | The *Business Corporations Act* (British Columbia). |
| **Board** | The board of directors of Entheon. |
| **CBCA** | The *Canada Business Corporations Act*. |
| **CDSA** | The *Controlled Drugs and Substances Act*, S.C. 1996 c. 19, as amended, including the regulations promulgated thereunder. |
| **CHDR** | The Contact Research Organization Centre for Human Drug Research |
| **CHDR Clinical Study Agreement** | The clinical trial agreement dated October 7, 2020 between Entheon and the CHDR. |
| **Computershare** | Computershare Trust Company of Canada, the registrar and transfer agent for the Entheon Shares. |
| **Consideration Shares** | Has the meaning ascribed thereto under the heading "*General Development of the Business – Events Subsequent to Fiscal Year Ended November 30, 2020*." |
| **Consolidation** | The consolidation of the issued and outstanding MPV Shares on the basis of three (3) pre-Consolidation MPV Shares for one (1) post-Consolidation MPV Share. |
| **CRO** | A contract research organization |
| **CSE** | The Canadian Securities Exchange. |
| **DMT** | N,N-dimethyltryptamine. |
| **DMT Delivery System** | Has the meaning ascribed thereto under the heading "*Description of the Business – Summary – DMT Delivery System."* |
| **DMT Products** | Has the meaning ascribed thereto under the heading "*Description of the Business – Summary – DMT Products."* |
| **DMT Solutions** | The DMT Delivery System and the DMT Products. |
| **EMA** | The European Medicines Agency. |
| **Entheon (or the "Company")** | Entheon Biomedical Corp., a corporation incorporated under the CBCA. |
| **Entheon Broker Warrants** | The broker warrants of Entheon exercisable to purchase Entheon Broker Warrant Units at an exercise price of $0.375 for a period of two years from the closing of the Subco Private Placement. |
| **Entheon Broker Warrant Unit** | A unit of Entheon compromised of one Enthon Share and one-half of one Underlying Entheon Broker Warrant. |

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| **Entheon Holdings** | Entheon Holdings Corp., the corporation formed as a result of the amalgamation of MPV Sub and Former Entheon in connection with the Amalgamation. |
| **Entheon Shares** | The common shares in the capital of Entheon. |
| **Entheon Warrants** | Common share purchase warrants of Entheon entitling the holders thereof to purchase Entheon Shares. |
| **Escrow Agreement** | The escrow agreement dated November 5, 2020, substantially in Form 46-201F1, entered into among the Escrowed Entheon Shareholders and Computershare, in relation to the Entheon Shares issued to the Escrowed Entheon Shareholders being held in escrow in connection with the Amalgamation. |
| **Escrowed Entheon Shareholders** | Each of Timothy Ko, Brandon Schwabe and Christopher Gondi, all of whom are subject to escrow restrictions pursuant to the Escrow Agreement. |
| **EU** | European Union. |
| **Exchange Act** | The United States Securities Exchange Act of 1934, as amended. |
| **FDA** | The United States Food and Drug Administration. |
| **Financing Warrant** | A Common share purchase warrant of Entheon entitling the holder to purchase an Entheon Share at a price of $0.60 for a period of two years from the date the Subscription Receipts were converted into Subco Units. |
| **Finders' Warrants** | Has the meaning ascribed thereto under the heading "*General Development of the Business – Events Subsequent to Fiscal Year Ended November 30, 2020*." |
| **Former Entheon** | Entheon Biomedical Corp. as it existed prior to completion of the Amalgamation, a private corporation incorporated under the BCBCA. |
| **Former Entheon Shares** | The Class A voting common shares in the capital of Former Entheon that were issued and outstanding prior to completion of the Amalgamation. |
| **GMP** | Good manufacturing practice. |
| **HaluGen** | Has the meaning ascribed thereto under the heading "*General Development of the Business – Events Subsequent to Fiscal Year Ended November 30, 2020*." |
| **HaluGen Shares** | Has the meaning ascribed thereto under the heading "*General Development of the Business – Events Subsequent to Fiscal Year Ended November 30, 2020*." |
| **Health Canada** | The Health Products and Food Branch of Health Canada |
| **Lobo** | Has the meaning ascribed thereto under the heading "*General Development of the Business – Events Subsequent to Fiscal Year Ended November 30, 2020*." |
| **Lobo Agreement** | Has the meaning ascribed thereto under the heading "*General Development of the Business – Events Subsequent to Fiscal Year Ended November 30, 2020*." |
| **MPV** | MPV Exploration Inc., the predecessor entity to the Company as it existed prior to the Amalgamation. |
| **MPV Shares** | Common shares in the capital of MPV, that were issued and outstanding prior to the Amalgamation. |
| **MPV Sub** | 1254912 B.C. Ltd., a corporation incorporated under the BCBCA, incorporated solely for the purposes of the Amalgamation. |

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| **MPV Warrants** | Common share purchase warrants of MPV, that were issued and outstanding prior to the Amalgamation. |
| **Ofichem** | Laboratorium Ofichem B.V. |
| **Ofichem Services Agreement** | The definitive services agreement dated May 4, 2021, by and between Entheon and Ofichem. |
| **Option Plan** | Has the meaning ascribed thereto under the heading "*Description of Capital Structure – Options*". |
| **Options** | Incentive stock options granted under the Option Plan. |
| **Psygen Supply Agreement** | The definitive supply agreement dated August 21, 2020, as amended on October 9, 2020, by and between Entheon Holdings and Psygen. |
| **Registrar** | The British Columbia Registrar of Companies appointed under the BCBCA. |
| **Securities Legislation** | The securities legislation of each of the provinces and territories of Canada and the Exchange Act and U.S. Securities Act each as now enacted or as amended and the applicable rules, regulations, rulings, orders, instruments and forms made or promulgated under such statutes, as well as the rules, regulations, by-laws and policies of the CSE. |
| **SEDAR** | System for Electronic Document Analysis and Retrieval. |
| **Subco Broker Exchange Ratio** | One Entheon Broker Warrant issued for each one Subco Broker Warrant, which holders of Subco Broker Warrants received in connection with the Amalgamation. |
| **Subco Broker Warrants** | The broker warrants exercisable into Subco Broker Warrant Units at an exercise price of $0.375 for a period of two years from the closing of the Subco Private Placement, that were issued to certain brokers under the Subco Private Placement. |
| **Subco Broker Warrant Unit** | A unit of MPV Sub comprised of one Subco Class A Share and one-half of one Underlying Subco Broker Warrant. |
| **Subco Class A Share** | A Class A non-voting common share in the capital of MPV Sub. |
| **Subco Finders' Unit** | A unit of MPV Sub comprised of one Subco Class A Share and one-half of one Subco Warrant, issued to certain finders in connection with the Subco Private Placement. |
| **Subco Unit** | A unit of MPV Sub comprised of one Subco Class A Share and one-half of one Subco Warrant. |
| **Subco Warrant** | Has the meaning ascribed thereto under the heading "*General Development of the Business - Events From March 31, 2020 to Fiscal Year Ended November 30, 2020*." |
| **U.S. Securities Act** | The United States *Securities Act of 1933*, as amended. |
| **Underlying Entheon Broker Warrant** | A Common share purchase warrant of Entheon entitling the holder to purchase an Entheon Share at a price of $0.60 for a period of two years from the date the Subscription Receipts were converted into Subco Units. |
| **Underlying Subco Broker Warrant** | A share purchase warrant of Subco entitling the holder to purchase a Subco Class A Share at a price of $0.60 for a period of two years from the date the Subscription Receipts were converted into Subco Units. |
| **United States** | The United States of America, its territories and possessions, any state of the United States and the District of Columbia. |

## 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.". On November 5, 2020, the Company completed a business combination (referred to herein as the Amalgamation) pursuant to which, among other things, Entheon Holdings completed a reverse takeover of MPV (now, "Entheon Biomedical Corp."). Pursuant to the Amalgamation, MPV changed its name to "Entheon Biomedical Corp." and Entheon Holdings became a wholly-owned subsidiary of the Company.

The Amalgamation constituted a "fundamental change" (as such term is defined in the CSE Policies) and the Entheon Shares began trading on the CSE on November 12, 2020 under the trading symbol "ENBI". The Entheon Shares also began trading on the Frankfurt Stock Exchange on November 26, 2020 under the symbol "1XU1."

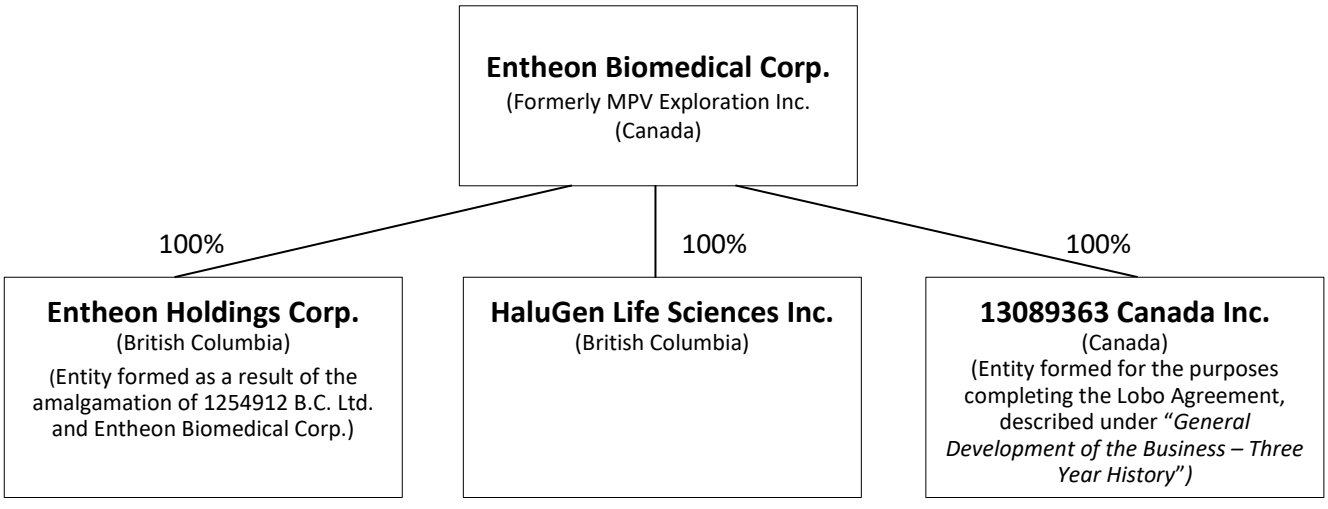
The head office of the Company is located at 211-3030 Lincoln Avenue, Coquitlam, BC, V3B 6B4 and the registered office is located at 10th Floor, 595 Howe Street, Vancouver, BC, V6C 2T5.

### 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 Amalgamation. 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 is the period 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 www.sedar.com 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:



## GENERAL DEVELOPMENT OF THE BUSINESS

### Three Year History

***Events Prior to Previous Fiscal Year Ended March 31, 2020***

Prior to completion of the Amalgamation, MPV had been engaged in the business of mineral exploration and the acquisition of mineral property assets in Canada and more specifically in the Chibougamau mining region of the Province of Quebec.

On March 31, 2017, MPV entered into an arm's length option agreement (the "**Property Option Agreement**") with Les Ressources Tectonic Inc. (the "**Optionor**"), to acquire a 100% interest a mineral resource property located alongside a provincial highway approximately 50 km west of the Town of Chapais, Quebec (the "**Mining Property**").

On April 24, 2018, MPV completed its initial public offering (the "**IPO**") whereby MPV issued an aggregate of 5,840,500 units (the "**IPO Units**") at a price of $0.20 per IPO Unit for gross proceeds of $1,168,100. Each IPO Unit was comprised of one MPV Share and one MPV Warrant, with each MPV Warrant being exercisable at a price of $0.30 for a period of two years. Leede Jones Gable (the "**IPO Agent**") acted as agent for the IPO and in connection therewith received a $116,810 cash commission and 584,050 broker warrants entitling the IPO Agent to acquire 584,050 IPO Units at a price of $0.20 until April 20, 2020.

On May 2, 2018, pursuant to the closing of the IPO, MPV issued an additional 125,000 IPO Units at $0.20 for gross proceeds of $25,000, for aggregate gross proceeds of $1,193,100 in its IPO. The new IPO units were issued under the terms of the over-allotment option granted to the IPO Agent.

On May 3, 2018 the MPV Shares began trading on the CSE under the symbol "MPV."

On June 12, 2018 MPV initiated a 1000-meter diamond drilling campaign on the West Bloc section of the Mining Property as MPV's first phase of MPV'S exploration program, budgeted at a total of $253,750.

On February 14, 2019 MPV completed a non-brokered private placement offering of 6,000,000 units (the "**February 2019 Units**") at a price of $0.08 per February 2019 Unit for aggregate gross proceeds of $480,000 (the "**February Offering"**). Each February 2019 Unit consisted of one MPV Share and one MPV Warrant with each MPV Warrant entitling the holder thereof to acquire one MPV Share at a price of $0.16 for a period of twenty-four months, expiring on February 12, 2021. In connection with the February Offering, MPV paid finder's fees totaling $23,750.

***Events from March 31, 2020 to Fiscal Year Ended November 30, 2020***

On April 3, 2020, MPV amended the terms of the Property Option Agreement for the Mining Property. Pursuant to the amendment, the balance of a $200,000 exploration expenditure obligation of MPV for the fourth and last year of the Property Option Agreement was entirely eliminated.

On June 30, 2020, MPV executed an amalgamation agreement (the "**Amalgamation Agreement**") with Former Entheon and MPV Sub, whereby MPV agreed to acquire all of the issued and outstanding shares of Former Entheon pursuant to a three-cornered amalgamation in accordance with Section 269 of the BCBCA, which would result in a reverse takeover transaction and a "Fundamental Change" of MPV as defined by CSE policies (the "**Amalgamation**"). Pursuant to the Amalgamation Agreement, Former Entheon agreed to amalgamate with MPV

Sub, a newly incorporated, wholly-owned subsidiary of MPV formed solely for the purpose of conducting the Subco Private Placement (defined below) and facilitating the Amalgamation.

On August 5, 2020 MPV disposed of all of its existing mineral resource properties, including MPV's rights under the Property Option Agreement as it relates to the Mining Property, which disposal was a condition to closing the Amalgamation. In this regard, MPV entered into a binding agreement following a tender process pursuant to which it agreed to sell its interest in the Mining Property for a cash consideration of $278,000. The sale was closed in escrow, pending completion of the Amalgamation.

On August 21, 2020, Former Entheon entered into the Psygen Supply Agreement with Psygen Labs Inc. ("**Psygen**"). Under the terms of the Psygen Agreement, Psygen will supply Former Entheon with non-GMP and GMP quality DMT for upcoming formulation, preclinical, clinical, and post-approval commercialization phases under the EMA regulatory framework. On October 9, 2020, the Psygen Supply Agreement was amended to clarify to the terms of the initial supply purchase order.

On September 9, 2020 MPV Sub completed a non-brokered private placement financing (the "**Subco Private Placement**") in connection with the Amalgamation, pursuant to which it issued an aggregate of 4,117,886 subscription receipts at a price of $0.375 (the "**Subscription Receipts**") per Subscription Receipt to raise aggregate gross proceeds of $1,544,207.25. The gross proceeds of the Subco Private Placement were deposited in escrow on the closing date to be released to MPV Sub upon MPV and Former Entheon having obtained approval of the Amalgamation by the CSE and completion of certain other administrative matters (the "**Release Conditions**"). Each Subscription Receipt was deemed to be exchanged upon satisfaction of the Release Conditions without payment of any additional consideration, for one Subco Unit. Each Subco Unit was comprised of one Subco Class A Share and one-half of one share purchase warrant of MPV Sub (each whole warrant, a "**Subco Warrant**"), which entitles the holder thereof to purchase a Subco Class A Share at a price of $0.60 for a period of two years from the date the Subscription Receipts were converted into Subco Units. In connection with the Subco Private Placement, MPV Sub paid certain cash finder's fees, issued an aggregate of 100,000 Finders' Units bearing the same terms as the Subco Units, and issued an aggregate of 211,297 Subco Broker Warrants, which were exercisable to acquire one Subco Broker Warrant Unit at an exercise price of $0.375 for a period of two years from the closing of the Subco Private Placement. Each Subco Broker Warrant Unit was comprised of one Subco Class A Share and one half of one Underlying Subco Broker Warrant, which entitled the holder thereof to purchase a Subco Class A Share at a price of $0.60 for a period of two years from the date the Subscription Receipts were converted into Subco Units.

On October 7, 2020, Former Entheon entered into the the CHDR Clinical Study Agreement with the Contract Research Organization, Centre for Human Drug Research ("**CHDR**") to conduct an early phase human clinical trial with DMT. Pursuant to the CHDR Clinical Study Agreement, Former Entheon contracted CHDR to carry out a study to evaluate the pharmacodynamics, pharmacokinetics and safety of a target-controlled intravenous infusion of DMT in humans.

On November 5, 2020 the Company closed the Amalgamation pursuant to which Former Entheon completed a reverse takeover of MPV. Immediately prior to the completion of the Amalgamation, MPV completed the Consolidation (a consolidation of the MPV Shares on the basis of one post-Consolidation MPV Share for every three pre-Consolidation MPV Shares). Pursuant to the Amalgamation, among other things: (i) Former Entheon amalgamated with MPV Sub under subsection 269 of the BCBCA to form Entheon Holdings; and (ii) shareholders of Former Entheon received one post-Consolidation MPV Share in exchange for each common share of Former Entheon held by such shareholder immediately prior to the effective time of the Amalgamation. After completion of the Amalgamation, the Company took over the business of Former Entheon and although the Amalgamation resulted in Entheon Holdings becoming a wholly-owned subsidiary of the Company, the Amalgamation constituted a reverse take-over of MPV because former shareholders of Former Entheon held

approximately 73.90% of the issued and outstanding Entheon Shares immediately after completion of the Amalgamation. Concurrently with the completion of the Amalgamation: (i) all of the issued and outstanding Subco Class A Shares were exchanged for Entheon Shares; (ii) all Subco Warrants were exchanged for Financing Warrants; and (iii) all Subco Broker Warrants were exchanged for Entheon Broker Warrants based on the Subco Broker Exchange Ratio. Upon closing of the Amalgamation, the Company changed its year end from March 31 to November 30.

On November 12, 2020 the Entheon Shares began trading on the CSE under the symbol “ENBI.”

On November 24, 2020, the Company completed a strategic investment of $50,000 in 2756407 Ontario Inc. (doing business as Wonder Scientific) ("Wonder Scientific"). Wonder Scientific's team of University Researchers and Product Development experts create custom, naturally derived, active pharmaceutical ingredients to supply the growing global clinical and commercial demand for psychedelics. The Company purchased unsecured convertible debentures (the “Debentures”) of Wonder Scientific pursuant to a non-brokered private placement, with each such Debenture having a principal amount of $25,000 and being convertible into common shares of Wonder Scientific. The Principal Amount of the Debenture will automatically convert into securities of the Wonder Scientific as follows on the earlier of: (i) upon satisfaction or waiver of all conditions precedent to the completion of a Going Public Transaction into common shares of Wonder Scientific at a deemed price per Common Share equal to a 20% discount to the price or deemed price attributed to the Common Shares pursuant to such Going Public Transaction; or (ii) the Maturity Date into Common Shares at a price per Common Share equal to the Conversion Price.

On November 26, 2020, the Entheon Shares began trading on the Frankfurt Stock Exchange under the symbol “1XU1.”

On November 27, 2020, Psygen successfully completed the production of a non-GMP DMT research batch for delivery to the Company's CRO, CHDR's partner pharmacy. The non-GMP DMT research batch was shipped to CHDR’s partner pharmacy on March 9, 2021.

***Events Subsequent to Fiscal Year Ended November 30, 2020***

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.

On December 9, 2020, the Company elected to exercise its option to purchase up to 9.9% of the common shares of Wonder Scientific. The Company paid an aggregate purchase price of $150,000 to exercise 937,500 shares of Wonder Scientific at an option exercise price of $0.16 per common share.

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. Immediately prior to the acquisition closing, the Debentures will be converted to common shares and as such, the holders of the Debentures will be treated as holders of Purchased Shares for purposes of the acquisition closing. 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 $3,174,374.25 (the "**December 2020 Placement**"). The majority of the December 2020 Placement was subscribed for by strategic investors. The Company allotted and issued 4,232,499 units (the "**December Units**") at a price of $0.75 per December Unit. Each December Unit is comprised of one Entheon Share and one-half of one non-transferable 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 Entheon Share, subject to accelerated expiry. In the event that, after four months and one day from issuance, the Entheon Shares trade at a closing price at or greater than $1.50 per Entheon 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 $126,367.43 and issued an aggregate 168,490 non-transferable finders’ warrants (the "**Finders’ Warrants**") to an arm's-length parties. Each Finders’ Warrant is exercisable into one December Unit for a period of up to two years at a price of $0.75.

On January 4, 2021 the Company entered into a business arrangement with, and made a strategic investment in, Heading Health, LLC ("**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 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 ketamine-assisted 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 below under the heading “*Description of the Business – Other Business Activities – EEG & Ketamine R&D – Further Investment into Heading Health*.”

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.

On January 11, 2021, the Company closed a second tranche of the December 2020 Placement for additional proceeds of $40,140.75. Pursuant to this second trance, 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 Life Sciences Inc. (“**HaluGen**”), a biotech company in the business of developing and commercializing a pre-screening test to identify genetic markers predictive of an individual’s reaction to hallucinogenic drugs. Pursuant to a share exchange agreement among the Company, HaluGen and the shareholders of HaluGen, the Company acquired all of the issued and

outstanding shares in the capital of HaluGen (the "**HaluGen Shares**") in exchange for 5,100,000 Entheon Shares issued to the shareholders of HaluGen (the "**Consideration Shares**") at a deemed price of $1.00 per Consideration Share. The Consideration Shares are subject to contractual restrictions on transfer, with 25% of the Consideration Shares released at closing of the acquisition, and 25% to be released on the dates that are 4, 8, and 12 months following the closing date of the acquisition, respectively. On February 24, 2021, Entheon announced that HaluGen's proprietary psychadelic's genetic test kit and technology platform had completed research and development and is nearing commercial production. In connection therewith, the Company also issued 900,000 Entheon Shares to Lobo Genetics Inc. pursuant to a production development agreement between the Company, Halugen and Lobo Genetics Inc. See below under the heading "*Description of the Business – Other Business Activities – Commercial Expansion of HaluGen*".

On January 19, 2021, the Company announced a partnership with Divergence Neuro Technologies Inc. ("**Divergence**"), a Company focused on the focused on the research and development of a data-driven, cloud-based neuro platform based on electroencephalogram ("**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 below under the heading "*Description of the Business – 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 below under the heading "*Description of the Business – 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. See below under the heading *"Directors and Executive Officers*".

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 March 3, 2021, the Company announced that it had appointed Nancy Maher as Special Advisory of Data Science and Regulatory Affairs to provide expertise on the development of the Company's data strategy design and study design and to advise on regulatory relationships on data strategy.

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 pre-clinical 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, HaluGen Life Sciences, Entheon's wholly-owned subsidiary, launched its psychedelics pre-screening platform and DNA test kit in Canada. The first of its kind psychedelics test kit provides genetic, personal and familial insights to better inform one's psychedelic assisted therapy experience. Entheon is exploring direct-to-consumer marketing partnerships with several commercial partners to accelerate awareness and growth of sales in multiple jurisdictions.

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, Entheon entered into the Ofichem Services Agreement with Laboratorium Ofichem B.V. ("**Ofichem**"). Under the terms of the Ofichem Services Agreement, Ofichem will 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 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.

On June 16, 2021, Entheon entered into an amalgamation agreement (the "**Lobo Agreement**") with Lobo Genetics Inc. ("**Lobo**") and 13089363 Canada Inc. ("**Subco**"), a wholly-owned subsidiary of Entheon. Lobo is a Toronto-based healthcare technology founded with the goal of helping people make informed choice around Cannabis through genetics, data and engagement. Lobo's proprietary genetic testing platform, the Lobo Cube, tests an individual's DNA for genetic markers related to cannabis metabolism, risk and impairment, including: (a) the body's ability to metabolize THC and CBD; (b) increased acute psychomimetic effects and long-term risk of cannabis-induced psychosis; and (c) neurocognitive impairment including short-term memory loss. At 4 inches cubed, the Lobo Cube can be deployed in clinics, pharmacies and retail outlets. Lobo has obtained an exclusive, perpetual worldwide license from Spartan Bioscience Inc., an Ottawa-based biotechnology and life sciences company, to use the Lobo Cube, and related intellectual property controlled by Spartan Bioscience Inc., for cannabis-related applications.

Pursuant to the Lobo Agreement, Lobo will amalgamate with Subco to form an amalgamated company, which will be a wholly-owned subisidiary of the Company named "Lobo Genetics Inc." ("**Amalco**"). It is anticipated that Timothy Ko, Entheon's Chief Executive Officer, President and a director of Entheon, will serve as the sole director of Amalco, which will carry on the business of Lobo. As consideration under the Lobo Agreement, the Company will issue an aggregate of 5,000,000 Entheon Shares (the "**Consideration Shares**") to the shareholders of Lobo. The Consideration Shares will be subject to contractual restrictions on transfer and will be released as to 25% on closing of the Lobo Agreement, with an additional 25% to be released at each 4-month anniversary of closing thereafter. In addition to the Consideration Shares, Entheon:

(a) will issue 9,603 stock options of the Company ("**Replacement Options**") to the holders of outstanding stock options of Lobo ("**Lobo Options**") in exchange for the exchange or conversion of the Lobo Options. Each Replacement Option will be exercisable to purchase one Entheon Share at

a price of $6.94 until the originally contemplated expiry date, in accordance with the original terms of the applicable Lobo Option; and

(b) may issue up to 46,944 common share purchase warrants (the "**Replacement Warrants**") to the holders of the outstanding common share purchase warrants of Lobo (the "**Lobo Warrants**") in exchange for the conversion, exchange or cancellation of the Lobo Warrants. Each Replacement Warrant will be exercisable for one Entheon Share at an exercise price of $13.89 until the originally contemplated expiry date, in accordance with the original terms of the applicable Lobo Warrant.

Completion of the Lobo Agreement is subject to a number of closing conditions, including approval of the directors and shareholders of Lobo, the resignation of the current directors of Lobo, and other required regulatory and third-party approvals required to complete the Lobo Agreement. Upon closing of the Lobo Agreement, John Lem, Founder and CEO of Lobo, will join Entheon's advisory board as a strategic advisory of industry affairs and will continue to advise and assist with the operations and strategic direction of Lobo and HaluGen.

**Business Outlook for the Upcoming Year**

Entheon intends to move forward in carrying out its strategies, meeting its business objectives and developing its business as described elsewhere in this AIF – see information under the heading "*Description of the Business*" for a description of Entheon's business. However, Entheon's strategies and business objectives may be impacted by changes in the global economy, the impact of COVID-19 on Entheon's operations, personnel and financial condition, the impact of COVID-19 on the operations, personnel and financial condition of the research partners and suppliers of Entheon, changes in legislation, changes in the psychedelic therapeutic industry, unanticipated costs and adverse novel discoveries regarding DMT.

**Significant Acquisitions**

Other than the Amalgamation described above under the heading "*Three Year History*," the Company has not completed any significant acquisitions during its most recently completed financial year for which disclosure is required under Part 8 of National Instrument 51-102.

## DESCRIPTION OF THE BUSINESS

**Summary**

Entheon is a biotechnology research and development company committed to developing and commercializing its DMT Products and DMT Delivery System (each defined below) for the purposes of treating addiction and substance use disorders. 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, the short acting and powerful nature of DMT make it the 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 Health Canada, the FDA nor the 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 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 question, 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 (as discussed in more detail under the heading "*Timing and Stage of Research and Development*.") 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 ability of each DMT Product to effectively treat the particular addiction or disorder it is intended to treat is both: (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 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 with the corresponding instructions to treat patients for their specific addictions.

***DMT Delivery System***

Furthermore, Entheon 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**"). 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. As discussed in further detail below under the heading "*Production*," the DMT Delivery System will employ existing target-controlled intravenous pump technology, typically used in analgesia and pain management, to administer Entheon's 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.

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, 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, in addition to sales derived from its DNA test kits.

***Summary of the Research and Development Process***

For the purposes of the following discussion, set forth below is a high-level overview of the research and development process (the "**Research and Development Process**") that a biotechnology research and development company typically must goes through in order to reach commercialization. The receipt of regulatory approval referred to in the Research and Development Process below is subject to a number of uncertainties and risks, including without limitation, risks relating to the inability of a company to meet the requirements for approval, adverse pre-clinical and clinical study results, changes in legislation, unanticipated costs and adverse novel discoveries regarding the specific therapeutic product/drug being developed. There is therefore no guarantee that a company will obtain all requisite approvals and reach commercialization by going through the following process:

1. engage various preclinical and clinical research partners needed to review existing literature and/or produce new data that will form the basis of product formulations ("**Product Formulations**") that make up a psychedelic therapeutic product;

2. upon completing the requisite research and analyzing the results, select the ingredients (including the active ingredients) required for a Product Formulation;

3. work with universities and/or CROs (companies that specialize in providing research services for biotechnology and pharmaceutical industries) to develop and design the Product Formulation and create several different dosing strategies to be tested in future clinical trials;

4. work with universities and/or CROs to develop and design clinical protocols ("**Clinical Protocols**") which are documents that describe 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;

5. submit the Product Formulations and the Clinical Protocols to applicable regulators for approval for use in clinical trials;

6. conduct clinical trials in accordance with the approved Clinical Protocols. Phase 1 trials are conducted first, to test the safety of new Product Formulations in human subjects and obtain basic pharmacology data; once safety is established, phase 2 trials are conducted to assess the efficacy of the Product Formulation at different doses for a given indication in a small (20-50) patient group; if phase 2 results show a significant therapeutic effect within a given dose range, phase 3 trials are conducted on a larger patient population, typically in the hundreds or thousands of subjects, across multiple clinical sites;

7. work with universities and/or CROs to prepare the following documents: (i) an investigational medicinal product dossier ("**IMPD**" or "**Investigational Medicinal Product Dossier**") 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 non-clinical and clinical studies, preclinical data from existing literature and internal studies and informed consent forms; (ii) an investigator's brochure ("**Investigator 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 which includes the Clinical Protocol; and (iii) a drug master file ("**Drug Master File**") which are submissions to regulatory authorities used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products.

8. develop a proof of concept, which is evidence, typically derived from experiments and clinical trials, which demonstrates that a design concept is feasible ("**Proof of Concept**");

9. submit the Proof on Concept to applicable regulators for market authorization and assignment of a Drug Identification Number; and

10. upon receiving all requisite authorizations, enter into the requisite agreements required for commercialization.

It is common for companies to concurrently engage in a number of the steps set out above. There is no certainty that a company will obtain regulatory approval after going through the foregoing Research and Development Process within any expected timeline or at all. Additionally, the above Research and Development Process is subject to potential delays, risks, changes and an increase in costs resulting from the on-going COVID-19 pandemic.

***Development Efforts to Date***

To date Entheon has, among other things: (i) completed an exhaustive literature review of materials confirming the efficacy of DMT and other psychedelic molecules for the purposes of treating mental health conditions; and (ii) assembled an arm's length advisory board of leaders in the field of this research (collectively referred to herein as the "**Science Advisors**"), who have both validated the conclusions relating to the efficacy of DMT and other psychedelic molecules, and informed Entheon's research processes. Additionally, Entheon is and has been working with its Science Advisors and various research organizations to, among other things: (i) develop its Dosing Strategies; (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.

*Dosing Strategies*

In order to eventually develop the DMT Products, Entheon must first develop the Dosing Strategies. In general, the purpose of developing effective drug Dosing Strategies is to achieve optimal drug efficacy. The ideal in drug therapy is to achieve the right dose, of the right drug, for the right time, in the right patient. Because DMT is a generic chemical that is not owned by anyone, Entheon's commercialization strategy is focused on using the drug in a novel way to produce effective therapeutic outcomes for addiction and substance use disorders. To that end, Entheon has begun by investigating how to both optimize the drug concentration and the duration of acute treatment (referred to herein as the Dosing Strategies) such that the end DMT Products will produce the desired outcomes. The efficacy of any particular Dosing Strategy depends not only on the DMT itself, but on the specific formulation of the DMT-based drug solution (which will likely contain a number of other ingredients), as well as the specialized equipment used to treat patients with the DMT Product in accordance with the Dosing Strategy. Entheon's plans to offer a comprehensive solution that includes unique DMT Products and a DMT Delivery System will be based in large part on the Dosing Strategies shown to be most effective in future clinical trials.

*DMT Research Conclusions*

Entheon's aim is to develop the Dosing Strategies such that it will optimize the effects of a type of psychedelic compound called tryptamines for the purposes of combating addiction and substance use disorders. Tryptamines include most of the well-known naturally-occurring psychedelics, including compounds derived

from psilocybin and psilocin, dimethyltryptamine, 5-methoxy-dimethyltryptamine, bufotenin, and ibogaine. After completing an exhaustive literature review of materials related to the efficacy of tryptamines for the purposes of treating mental health conditions, including a review of certain indigenous practices, Entheon has concluded that these molecules may assist in the treatment of substance use disorders. While Entheon is investigating a range of tryptamines, at this time it is primarily focused on using DMT in the development of its Dosing Strategies and DMT Products.

As a result of the research conducted to date on the above tryptamines, Entheon has conceptualized several Dosing Strategies that will be validated in planned human trials. The Dosing Strategies developed to date, in part, endorse the delivery of a DMT-based therapeutic product via controlled intravenous infusion that slowly and gradually increases the rate of drug material administered to the patient allowing them to arrive at a therapeutic range. This novel method of administration carries with it the combined benefit of gradual immersion, so as not to overwhelm the recipient, as well as the ability to rapidly end the experience in the event of a negative adverse reaction. These two qualities have not been previously combined. The Dosing Strategies, as part of the clinical DMT Protocol, is intended to have specific therapeutic applications that target addiction and substance-related disorders. If regulatory approval is received, the DMT Products (which will incorporate the Dosing Strategies) will initially be patented and sold in the European Union, Canada and the United States.

*Literature Review*

A systematic review of the scientific literature was conducted to understand the current state of DMT research and provide a foundation for Entheon's clinical pipeline and product development efforts. Public databases searched include PubMed, MEDLINE, and Google Scholar; additionally, specialized toxicity databases were also accessed by regulatory consultants. All clinical and nonclinical studies performed with DMT since its first synthesis in 1931 were compiled and organized by subject, and the results were analyzed to extract and summarize relevant data, including, but not limited to, dose forms, routes of administration, pharmacokinetic parameters, neuroimaging results, and adverse effects. From this review Entheon has acquired an extensive understanding and built a comprehensive internal database of DMT literature. Entheon has also conducted a vast amount of research on other psychedelic drugs including DMT, 5-MeO-DMT and Ayahuasca (a South American entheogenic brew commonly made out of the Banisteriopsis caapi vine, the Psychotria viridis shrub or a substitute).

*Non-Clinical Development*

Non-clinical development efforts undertaken by the Company to date include: (i) identifying and partnering with licensed and accredited drug manufacturers, including Psygen Labs (Canada) and Ofichem B.V. (Netherlands) for the production and shipment of GMP certified DMT to accredited CROs engaged by Entheon to conduct chemical analysis and nonclinical research; (ii) forming relationships with third-party laboratories for chemical analysis and long-term stability studies; (iii) assessing the need for preclinical animal studies given DMT's long history of human use; and (iv) designing and implementing *in vitro* (outside of living organisms) and *in vivo* (inside living organisms) assays deemed essential for regulatory approvals. Nonclinical activities occur in parallel with clinical development, and both have required extensive collaboration among Entheon's executive team, scientific advisors and consultants.

*Clinical Development*

To date, clinical development efforts have been specifically focused on: (i) designing a robust experimental DMT Protocol to test Entheon's Dosing Strategies in humans; (ii) engaging the Centre for Human Drug Research, a research organization to carry out this design in a double-blind, randomized, placebo-controlled clinical trial

referred to herein as the Phase I Study; and (iii) working with Entheon's Science Advisors and clinical partners to create and refine the experimental design of the Phase I Study. The current design will establish clinical safety for the Dosing Strategies, collect a range of data for development of the DMT Delivery System, identify the target dose range for substance use applications, and establish preliminary efficacy for nicotine addiction. Together, these elements will inform the final DMT Protocol to be prototyped and tested in subsequent clinical trials. To this end, a clinical study protocol is actively under development in collaboration with Johns Hopkins University and Imperial College of London Advisors.

*Development Efforts*

Development efforts to date have included: (i) the creation of a target product profile for the proposed use of the Dosing Strategies for various indications; (ii) discussions with prospective manufacturing partners for different components of Entheon's DMT Delivery System and related monitoring devices; (iii) the integration into the DMT Protocol of environmental factors and other aspects of "set and setting" (being the physical and social environment in which a user has a psychedelic drug experience); (iv) consultation with experts in psychiatric protocols to implement a safe and an appropriate therapeutic framework for administration of the Dosing Strategies; (v) the establishment of relationships with clinician networks for commercial deployment of the final DMT Protocol; and (vi) the creation of Entheon's product brochure.

*Regulatory Strategy*

Because a deep understanding of the regulatory framework in multiple jurisdictions (FDA, EMA, and Health Canada) is necessary for efficiently obtaining drug product approvals, Entheon has engaged regulatory experts from its earliest stages in order to identify roadblocks and prepare itself to move efficiently through each regulatory system. Entheon has also expended resources on working with its Science Advisors to develop a specific regulatory strategy in the European Union. Lastly, Entheon has deployed resources on the development of major regulatory documents including: (i) the Investigator's Brochure; (ii) the Investigational Medicinal Product Dossier; and (iii) the Drug Master File, all of which are explained in further detail under the heading "*General Development of the Business – Summary of the Research and Development Process*". The Investigator's Brochure has been drafted and is currently under review by CHDR, while the IMPD and the Drug Master File are currently under development by Entheon's expert consultants, advisors, and clinical partners as part of the lead-up to the Phase I Study.

*Patent Prosecution and Portfolio Development*

Entheon has expended financial resources of patent prosecution including with respect to: (i) the filing of four provisional patent applications with the United State Patent and Trademark Office relating to Entheon's Dosing Strategies and the DMT Delivery System (as discussed in further detail under the heading "*Intellectual Property – Patents*"); and (ii) the execution of associated contracts and the development of associated reports related to the conceptualization and legal protection of the Dosing Strategies and DMT Delivery System. Additionally, Entheon has expended financial resources on portfolio development which consists of the exploration of new technologies using novel compounds and alternative methods of administration.

***Timing and Stage of Research and Development***

Entheon plans to follow the strict regulatory pathways of classic drug discovery and approval. In doing so, as described in further detail below, Entheon is in the process of engaging various research organizations to conduct a number of preclinical and clinical studies of which involve, and will inform the development of, the

Dosing Strategies and the DMT Protocol. The results of these studies, among other relevant data, will thereafter form the basis of Entheon's regulatory submissions.

As discussed in further detail under the heading "*Intangible Properties – Patents,*" Entheon has filed four provisional patent applications with the United States Patent and Trademark Office that relate to the Dosing Strategies and the DMT Delivery System. Concurrently as Entheon moves through the patent approval process and continues to prepare to submit additional patent applications, Entheon is engaged in the following activities in the clinical testing and regulatory approval process, the timing and costs of which may be impacted by COVID-19 and any related regulatory delays and changes (discussed further under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*"):

1. **Sourcing the Drug Products**. Entheon has entered into supply agreements with two chemical manufacturing organizations in North America and in Europe, which will provide Entheon with the Drug Products (GMP quality and non-GMP DMT drug products and substances) for its preclinical, clinical and post-approval commercialization phases. 1) Psygen Labs, located in Alberta, Canada, is licensed by the Health Canada Office of Controlled Substances to manufacture, sell and export DMT. The Psygen Supply Agreement is governed by the laws of the province of Alberta and the laws of Canada applicable therein. The Psygen Supply Agreement expires upon the latter of (i) ten years from the effective date of the Psygen Supply Agreement; and (ii) completion of the Study (as defined in the Psygen Supply Agreement), unless otherwise terminated by either party in accordance with Article 15 of the Psygen Supply Agreement, provided that the term will continue to apply as necessary in respect of outstanding payments owed in accordance with the Psygen Supply Agreement. The term of the Psygen Supply Agreement will automatically be extended for one additional period of five years unless either Psygen or Entheon provides notice in writing that it has elected not to extend the term at least six months prior to the end of the term. Under the Psygen Supply Agreement Entheon is obliged to pay to Psygen an aggregate of USD$40,000 for the initial supply purchase order of the Drug Products to be used for the Phase I Study. Within the timeframes specified in the Psygen Supply Agreement, the parties shall negotiate the purchase price and the break fee for all other clinical trial phases to follow. In each case, the purchase price shall be increased based on reasonable good-faith negotiation by the parties. 2) Ofichem B.V., located in Ter Apel, Netherlands, has also been contracted by Entheon to produce GMP-quality DMT substance, as a secondary source of material for the Phase I Study. Ofichem is licensed in the Netherlands to produced GMP-quality DMT, and has existing relationships with both the Centre for Human Drug Research and the Leiden University Medical Centre. Under the Ofichem Services Agreement, Entheon has agreed to pay Ofichem an aggregate of €98,520 in exchange for Ofichem synthesizing, validating and producing GMP quality DMT for use in the Phase I Study.

2. **Review by Dutch Regulators.** The Netherlands' Central Committee on Research Involving Human Subjects (an organization established under the Dutch *Medical Research Involving Subjects Act*, "**CCMO**") is currently reviewing the Investigator's Brochure in conjunction with CHDR. They will be evaluating the Investigator's Brochure as it develops in order to inform Entheon's clinical and regulatory approach prior to bringing it before the CCMO later in 2021.

3. **Conducting the Preclinical Studies.** Entheon is preparing to initiate preclinical studies with accredited CROs to assess the chemical stability of the Drug Products received from Psygen and to obtain baseline toxicology and safety data in animals (the "**Preclinical Studies**"). Following a comprehensive review of the existing DMT literature, Entheon intends to limit the Preclinical Studies to an investigation of intravenous toxicity and cardiovascular effects and are not likely to require the exhaustive approach for new molecular entities. As of the date hereof, Entheon has entered into an agreement with Science in Action, based in Ness Ziona, Israel, to perform basic toxicity assays with DMT. Entheon is also evaluating additional candidate CROs in Israel, Canada, and the United States, any of which would be able to rapidly

conduct standard preclinical studies if requested by regulators during the clinical trial application review process. Entheon will always work with a CRO that maintains the applicable regulatory approvals, including the applicable controlled substance exemptions, required to complete the Preclinical Studies, such that Entheon will not be required to obtain any regulatory approvals or permits itself.

- **Cost:** The costs of the Preclinical Studies, if required based on the opinions of Entheon's clinical partners and regulatory consultants, will be determined by reasonable good-faith negotiation of the parties and the billing will occur as work is conducted. A basic toxicological assessment for DMT may include in vitro cardiovascular safety and genotoxicity studies, as well as studies of acute intravenous toxicity in rats, at an approximate cost of $50,000.

- **Objectives:** to the test the efficacy and safety of the Dosing Strategies in animals.

- **Outcome Measures:** Given that much is already known about DMT's safety profile, with over 50 years of animal studies in the published literature, Entheon expects that the Preclinical Studies may comprise limited i*n vitro* (outside a living organism) and *in vivo* (on a living organism) studies. In preparation for the Phase 1 study, these studies are expected to be minimally necessary and limited to *in vitro* cardiovascular safety screening and *in* vivo acute intravenous toxicity studies. If requested by regulatory authorities, additional tests may include single dose toxicity in rats, maximum tolerated dose study in dogs, Irwin screen test in rats, and respiratory safety pharmacology studies. Full 28-day toxicity studies in rats and/or dogs are highly unlikely to be needed. Behavioural experiments are expected to follow shortly thereafter to determine if the administration of Entheon's Dosing Strategies yields reductions in drug seeking behavior, and increased sociability in its test animals.

4. **Development of DMT Products.** Entheon will need to develop the DMT Products in a form that can be administered by intravenous therapy or other routes in clinical trials, which is expected to occur late in 2021 and onwards and to be initially done by the production pharmacy at CHDR. Further development of the DMT Products to a commercialization stage will be ongoing and dependent on the Dosing Strategies data obtained in planned phase I and 2 clinical trials. This will have an estimated cost of $70,000 in the next 12 months and an additional ongoing cost of $260,000 to the end of 2024.

5. **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) will be assessed over a period of several months. This is done to ensure that the form of the drug delivered to patients is of the same purity as the original drug substance, sterile and free of contamination by chemical degradation products, and will be performed on each batch of drug shipped by Psygen.

6. **DMT Assay Development.** In advance of clinical trials, an analytical chemistry method must be developed to measure DMT and its metabolites in blood or plasma samples obtained from trial participants at various time points. This method will be developed in collaboration with an appropriate analytical laboratory designated as a sub-processor under agreement with the clinical trial site, described below. Estimated cost: $100,000.

7. **Clinical Trial Insurance.** Although insurance for the clinical site is included in the CHDR Clinical Study Agreement, Entheon will purchase additional insurance to cover any additional liability to the company that may result from unanticipated adverse events. This will be obtained following the finalization of the DMT Protocol and regulatory submission documents, currently targeted for mid-2021. Estimated cost is $50,000.

8. **Developing a Clinical DMT Protocol and Conducting the Phase I Study.** Entheon is working with CHDR, a CRO that specializes in providing research services for biotechnology and pharmaceutical industries, in order to develop different Dosing Strategies and design Entheon's DMT Protocol. In connection therewith, Entheon has entered into the CHDR Clinical Study Agreement to perform the Phase I Study scheduled to take place in the Netherlands in late 2021, subject to potential delays discussed under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*" and to the completion of the Preclinical Studies necessary prior to the Phase I Study. The terms of the CHDR Clinical Study Agreement are set forth under the heading "*Description of the Business – Summary – Economic Dependence*."

    - **Cost:** Entheon has agreed to pay CHDR an estimated fee of €927,314 for completion of the Phase I Study. Entheon paid an initial €133,722 upon signing the contract for study setup costs and 10% clinical costs. The estimated remaining fee for completion of Phase I Study is €793,592.

    - **Description:** It is critical for Entheon to provide evidence for the efficacy and safety of the DMT Protocol. The Preclinical Studies are essential to this because they provide the ability to quickly evaluate a drug's characteristics in animals, including physiological and biochemical processes, such as adverse effects and interactions that cannot be observed *in vitro* or in human subjects. In addition, animal data (which will be obtained from the Preclinical Studies) is often required by regulatory authorities before human trials are approved. In order to provide preliminary efficacy data for nicotine addiction, the Phase I Study will recruit healthy nicotine users as subjects. Together, these data will be put toward regulatory approval applications (as described further below) and will inform larger phase 2 and 3 efficacy trials.

    - **Objectives:** The Phase I Study will determine the pharmacokinetic and pharmacodynamic properties of Entheon's Dosing Strategies, and will collect a range of neurological, cardiovascular, and immunological data to assess drug tolerance, safety and subjective effects. Pharmacodynamics refers to the biochemical and physiologic effects of a drug; pharmacokinetics includes the movement of a drug into, through, and out of the body — the time course of its absorption, bioavailability, distribution, metabolism, and excretion. The study will utilize a randomized, placebo controlled design to establish optimal dose range and duration for therapeutic efficacy and assess safety and minimally effective and maximally tolerated doses.

    - **Outcome Measures**: The results of the Phase I Study are expected to, among other things: (i) determine the concentrations of DMT in blood plasma required to maintain steady-state DMT effects using target-controlled intravenous infusion; (ii) characterize the incidence and severity of adverse events associated with increasing doses of DMT in a normal adult; and (iii) assess the effectiveness of DMT intervention, within the context of an addiction therapy program, on nicotine addiction in otherwise healthy subjects.

***Additional Steps Required for Development & Commercialization***

It is Entheon's objective to conduct the following additional steps in the next 12 months, subject to the risks, delays and related cost implications discussed under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*". The following additional steps are required to fully develop and commercialize the DMT Products for the purposes of treating nicotine addiction. Subject to any impact that COVID-19 may have on Entheon's personnel and business operations, no additional costs will be incurred for this work as it is to be performed internally.

- **Submissions to Regulators.** Entheon is in the process of preparing certain regulatory documentation and submitting it to: (a) the FDA; (b) the EMA; and (c) Health Canada. Entheon has drafted the Investigator's Brochure, which has undergone preliminary review by CHDR. Entheon is also in the process of preparing an IMPD. As discussed in further detail under the heading "*Description of the Business – Summary – Summary of the Research and Development Process*", the IMPD and the Investigator's Brochure are comprised of all chemistry, manufacturing and control data for the drug itself, preclinical data from existing literature and internal studies, informed consent forms, and the DMT Protocol itself. The IMPD will be submitted to the Dutch human ethics committee prior to the Phase I Study and later will form part of Entheon's EMA submissions. The IMPD, along with the Investigator's Brochure and the Phase I Study trial results will then be submitted to the FDA in the form of a Drug Master File.

It is Entheon's objective to conduct the following additional steps beyond 12 months after the date hereof, subject to the risks, delays and related cost implications discussed under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*". Entheon will require additional sources of financing in order to fund the steps set forth below.

- **Meeting with FDA.** Entheon will need to meet with the FDA to outline a path for a potential Phase 2 Nicotine Study of DMT for nicotine addiction in the United States.

- **GMP Drug Synthesis**. Drug synthesis is the artificial execution of useful chemical reactions to obtain one or several products. Along with this Entheon will scale-up to larger batches of drug material through a commercial partner for conducting future phase 3 trials. GMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. Pricing varies by clinical stage and scale up capacity is contingent on Psygen's license restrictions.

- **Further Development of DMT Products.**

- **DMT Delivery System development.** This will include the selection and optimization for intravenous pumps, monitoring devices and auxiliary components, including set and setting components;

- **Integration of the Dosing Strategies with The DMT Protocol (as further developed).** Standard cognitive behavioral therapy for treating substance use disorders will be adapted for psychedelic-assisted therapy using the Dosing Strategies.

- **Phase 2 Nicotine Study.** Upon completion of, among other things, the Phase I Study, Entheon intends to complete an additional clinical study in the United States focused on addressing nicotine addiction (the "**Phase 2 Nicotine Study**").

    - **Description:** The Phase 2 Nicotine Study will include submission of regulatory documents to the EMA, preparation of the Phase 2 Nicotine Study site, initial study subject recruitment & enrolment, development and implementation of a randomized, placebo controlled, blinded study design, analytical/bioanalytical chemistry tests, analysis of study results, standard statistical tests, advanced pharmacokinetic and pharmacodynamic population modelling & simulation, preparation of the final study report, and the Phase 2 Nicotine Study site closure.

- **Objective:** The objective of the Phase 2 Nicotine Study is to further demonstrate the safety and efficacy of the Dosing Strategies as applied to address nicotine addiction (as amended after completion of the Phase I Study).

- **Outcome Measures:** The Phase 2 Nicotine Study is expected to, among other things: (i) compare measures of neuronal activity and complexity between subject groups; (ii) obtain cardiovascular and immunological health data; (iii) assess improvements in objective measures of wellbeing via interviews and questionnaires; (iv) evaluate frequency and severity of adverse effects; and (v) determine rate of nicotine use following DMT-assisted therapy via questionnaire and/or biomarkers.

- **Nicotine Addiction Multicenter Study (Phase 3 Study).** The phase 3 study consists of an expanded pilot study to multiple clinics to assess treatment outcomes in larger populations of nicotine users, including specific indications.

**Regulations**

Set forth below is a discussion of the current legal framework and applicable legislation relating to DMT and Entheon's operations in each of Canada, the United States and Europe.

***Drug Scheduling Regulations***

*Canada*

Certain psychoactive compounds, such as DMT, are considered controlled substances under the CDSA (*Canada Controlled Drugs and Substances Act*). Specifically, DMT (3–[(2–dimethylamino) ethyl]indole) and any salt thereof, are listed under Schedule III of the CDSA. The possession, sale or distribution of controlled substances is prohibited unless specifically permitted by the government. Penalties for contravention of the CDSA related to Schedule I substances are the most punitive, with Schedule II being less punitive than Schedule I, Schedule III being less punitive than Schedule I and II and so forth. A party may seek government approval for a Section 56 Exemption to allow for the possession, transport or production of a controlled substance for medical or scientific purposes, as discussed in further detail below under the heading "*Regulatory Approvals Required for Studies – Canada.*"

Health Canada regulates all health products in Canada, and a health product may only be sold in Canada with the permission of Health Canada. During its evaluation of the safety, efficacy and quality of each health product, Health Canada determines whether a drug should be a controlled substance, a prescription drug or a non-prescription drug. A substance may be deemed a controlled substance but also a prescription drug. As discussed above, scheduling the substance in the CDSA means that there are criminal consequences to possessing the drug unlawfully. If Health Canada determines that a drug requires a prescription, it is placed on the Health Canada Prescription Drug List ("**PDL**"). DMT is not currently on the PDL.

After Health Canada determines if a drug may be sold in Canada and if it requires a prescription, the individual provinces, territories and the National Association of Pharmaceutical Regulatory Authorities ("**NAPRA**") decide where it may be sold, under advisement from the National Drug Scheduling Advisory Committee ("**NDSAC**"). NAPRA maintains a harmonized list referred to as the National Drug Schedules. NAPRA may decide to be more restrictive in scheduling drugs, but never less restrictive than has already been determined at the federal level.

*United States*

As explained in further detail below, DMT is currently a restricted drug under the CSA (United States *Controlled Substances Act* of 1970). In the United States, clinical trials involving restricted drugs must adhere to the CSA and its implementing regulations, which are enforced by the Drug Enforcement Agency ("**DEA**") under a legislative, regulatory, and enforcement structure and process. State regulations of controlled substances frequently change, so it is important to be aware of the regulatory nuances of each state in which a trial is conducted. There are three agencies – the FDA, the National Institute on Drug Abuse, and the DEA – involved in the scheduling of controlled substances, including both narcotic drugs and psychotropic substances.

Controlled substances are categorized by the DEA according to five schedules, based upon eight factors, including: 1) actual or relative potential for abuse; 2) scientific evidence of pharmacological effect, if known; 3) state of current scientific knowledge about the drug; 4) history and current pattern of abuse; 5) scope/duration/significance of abuse; 6) what, if any, risk to public health; 7) psychic or physiological dependence liability; and 8) whether the substance is an immediate precursor of an already controlled substance.

DMT is listed as a Schedule I substance under the *United States Code of Federal Regulations Title 21 – Food and Drugs 21 Part 1308.11* and assigned DEA Controlled Substances Code Number 7435. Schedule I substances are described as those that have the following findings:

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.

No prescriptions may be written for Schedule I substances, and such substances are subject to production quotas which the DEA imposes. All principal investigators or sub-investigators (typically a member of a university or CRO) involved in a clinical trial using a controlled substance must obtain both federal and state authorizations. DEA registration and state licensure are required at the general physical location where the controlled substances for the clinical trial will be dispensed and/or stored overnight. In some cases, it may be possible to dispense the study drug at a satellite location with a separate license and registration if there is no overnight storage at that satellite location.

Federal registration is granted by the DEA. DEA "Practitioner" registration is valid for three years although Schedule I substances such as DMT require a DEA "Researcher" registration, valid for one year only, and in this situation, the research protocol must be formally approved by the FDA prior to registration with the DEA. All practitioners who participate in a clinical trial as a principal investigator or sub-investigator must also be authorized by the state in which they practice to prescribe, dispense, administer, and conduct research with controlled substances. In most cases, these activities are authorized when a license is granted to the practitioner by the local Institutional Review Board. However, some states require a separate, state-issued controlled substance license and other states have a separate state-controlled substances authority that requires practitioners to obtain a separate registration, in addition to their board license.

*Europe*

The International Narcotics Control Board ("**INCB**"), a United Nations ("**UN**") entity, monitors enforcement of restrictions on controlled substances. The INCB's authority is defined by three international UN treaties – the *UN Single Convention on Narcotic Drugs of 1961*, the *UN Psychotropic Convention of 1971* (referred to herein as the UN71), and the *UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988*,

which contains provisions related to the control of controlled substance precursors. European Union (EU) Member States, including the Netherlands, that have agreed to abide by the provisions of these treaties, each create responsible agencies and enact laws or regulations to implement the requirements of these conventions.

Specific EU legislation establishing different classes of controlled substances is limited to EU regulations that define classes of precursors, or substances used in the illicit manufacture of controlled substances, including *Regulation (EC) No. 273/2004* of the European Parliament and the Council of February 11, 2004 and the *Council Regulation (EC) No. 111/2005 of December 22, 2004*. While EU legislation does not establish different classes of narcotic drugs or psychotropic substances, the Council Decision 2005/387/JHA of May 10, 2005 can provoke a Council Decision requiring EU member states to put a drug under national controls equivalent to those of the INCB. DMT is currently classified as a Schedule I substance under the UN71; the EU member states, including the Netherlands, have agreed to the following in respect of Schedule I substances:

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

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

***Regulatory Approvals Required for Studies***

Regulatory approvals are required for clinical (human) studies for all investigational products in all member countries of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, which includes the United States, Canada and EU member states.

*Canada*

In order to conduct any scientific research, including pre-clinical (animal) and clinical (human) trials using a controlled substance (such as DMT) in Canada, a party must either: (i) obtain an exemption under Section 56 of

the CDSA; (ii) hold a dealer's license under Part J of the *Canada Food and Drug Regulations* ("**Canada FDR**"), each of which are described further below:

- Section 56 Exemption - This exemption allows the holder to possess and use the controlled substance without being subject to the restrictions set out in the CDSA, subject to obtaining any additional approvals such as ethics and clinical trial approvals. Specifically, the final approved clinical study protocol and a Health Canada issued No Objection Letter are required to obtain an exemption under subsection 56(1) of the CDSA to conduct clinical investigations with DMT in Canada.

- Dealer's license under the Canada FDR – This license allows the party to produce, assemble, sell, provide, transport, send, deliver, import or export a restricted drug (as listed in Part J in the Canada FDR– which includes DMT), assuming compliance with all relevant laws (the CDSA and Canada) and subject to any restrictions placed on the license by Health Canada. In order to qualify as a licensed dealer, a party must meet all regulatory requirements mandated by the regulations including having compliant facilities, compliant materials and staff that meet the qualifications under the regulations of a senior person in charge and a qualified person in charge.

*United States*

The DEA has a streamlined application process for researchers who wish to conduct clinical trials using a Schedule I substance not currently approved for medical use (such as DMT). Schedule I substances are defined as drugs, substances, or chemicals with no accepted medical use and a high potential for abuse. Applicants must provide information about their qualifications, research protocol, and institution where the research will take place; complete requirements are outlined in the U*nited States Code of Federal Regulations Title 21 – Food and Drugs 21 Part 1301.18*.

*Europe*

Refer to the discussion above under the heading "*Drug Scheduling – Europe*" for a general description of the regulatory requirements to conduct research and clinical and pre-clinical studies using a Schedule I substance such as (DMT) in one of the EU member states. The specific regulatory processes and approvals required may vary among different EU member states and are set forth in the respective legislation of each country. For The Netherlands, there are specific regulatory requirements for the approval of clinical trials that need to be met. Firstly, a Clinical Trial Application ("**CTA**") dossier containing the preclinical and any clinical information along with the proposed clinical trial design must be submitted to an accredited Ethics Committee and to the CCMO (the Central Commission on Research in Humans), which is also known as the Competent Authority in The Netherlands. In Dutch, the CCMO is called the 'Centrale Commissie Mensgebonden Onderzoek'. In cases where the study involves a substance subject to the *Dutch Opium Act* (such as DMT), an official exemption by Farmatec (in Dutch) is needed, which needs to be included in the CTA. By law, the CCMO performs an abbreviated CTA review within 14 days of the submission. They will provide the applicant with a notification of no objection, pending full review by an accredited and independent Ethics Committee at the institution where the clinical trial is to take place. The full review of the CTA dossier is delegated to the Ethics Committee; the trial can only start when a favorable opinion is received from the Ethics Committee and a statement of no-objection from the CCMO have been obtained. The timeline for ethics review is 60 days maximum, but will be 14 days for Phase I studies within the Netherlands. During this time, the Ethics committee can request additional information. Prior to operating or conducting any pre-clinical or clinical studies in any other EU member state, Entheon will investigate the specific regulatory requirements of such EU member state.

***Other Health and Drug Product Regulations***

Because Entheon only seeks prescription status for its DMT Products, non-prescription drug product related regulations will not apply. Seeking regulatory approval for non-prescription status of a controlled substance like DMT is unlikely to yield favourable results with regulators, particularly in the United States where DMT is listed as a Schedule I substance. Additionally, natural health products related regulations will not be applicable to Entheon, as the DMT to be used in its DMT Products will be chemically synthesized to GMP standards rather than produced from natural sources.

***Other Product Regulations***

Entheon's operations are subject to various laws, regulations, and guidelines by governmental authorities, particularly Health Canada, the FDA and the EMA relating to the manufacture, marketing, management, transportation, storage, sale, pricing and disposal of consumer products, as well as laws and regulations relating to health and safety, insurance coverage, the conduct of operations, and the protection of the environment.

*Canada*

The applicable regulations in Canada that Entheon will be subject to with respect to labeling the DMT Products are the *Canada Food and Drugs Act* (the "**Canada FDA**"), the Canada FDR and the CDSA. Additionally, the *Canada Consumer Packaging and Labelling Act* ("**CPLA**") may be applicable although the required statements pertaining to medical products are covered in the Canada FDA and Canada FDR. The Canada FDA and Canada FDR regulate food and drugs in Canada and set forth requirements on composition (including but not limited to food additives, fortification, and food standards), packaging, and licensing requirements. Entheon is not required to obtain pre-approvals or licenses for its products, but must comply with the Canada FDA's production, packaging, labelling and marketing requirements, which include ensuring that its products are not packaged or marketed in a manner that is misleading or deceptive to a consumer. The FDR further requires most food products to display specific nutrition facts and nutrient content on their labels in the form of a Nutrition Fact Table ("**NFT**"). The FDR was amended on December 14, 2016 to introduce new nutrition labelling regulations, including a five-year transition period to meet the new requirements. The transition period will end on December 14, 2021, and inspection activities will monitor compliance with the new regulations. The Canadian Food Inspection Agency is responsible for compliance with and enforcement of the new requirements. The CPLA provides for a uniform method of packaging and labelling pre-packaged consumer goods in Canada. The relevant provisions include prevention of misleading statements and requiring certain information to be included on the labels.

*United States*

The packaging and labeling requirements for drug products in the United States are governed by *the United States Code of Federal Regulations, Title 21--Food and Drugs - Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter C—Drugs* ("**CFR 21**"): *General Part 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals*, and Parts 201, 314 and 610 which set out specific labelling requirements for medical products. Generally, under this legislation, there shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features: (i) prevention of mix-ups and cross-contamination by physical or spatial separation from operations on other drug products; (ii) identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots; (iii) identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch; (iv) examination of packaging and labeling materials for suitability and

correctness before packaging operations, and documentation of such examination in the batch production record; and (v) inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Additionally, labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification and access to the storage area shall be limited to authorized personnel. Specifically, CFR 21 sections 201.56 and 201.57 outline the general and specific requirements on the content and format of the Physician Labeling Rule (as defined therein) for prescribing information, finalized in 2006. The FDA has further issued a number of guidance documents to aid preparing structured product labelling for submission as part of a new drug application.

*Europe*

In Europe, the EMA provides guidance and templates, to applicants looking to receive market authorization for their drug product, with practical advice on how to draw up the product information for human medicines, which includes the summary of product characteristics, labelling and package leaflet. EMA's guidance explains the content that should be included in these documents, as well as standard headings and the most commonly used standard statements and terms in all official European Union languages plus Icelandic and Norwegian, and defines the format and layout for the product information. EMA's guidance is without prejudice to: any final positions from the EMA, the Committee for Medicinal Products for Human Use or European institutions relating to the contents of the documents; the binding nature of the relevant legislation; any legal interpretations given by the European Commission or the Court of Justice of the European Union. Specific requirements for labelling are outlined in Regulation *(EC) No 726/2004 and Directive 2001/83/EC of the European Parliament*.

***Clinical Studies and Market Authorization Regulations***

Entheon's goal is to ultimately get market authorization from Health Canada, the FDA and the EMA to sell its DMT Products in Canada, the United States and the European Union, respectively. However, prior to doing so Entheon will need to go through the clinical study regulatory process to have its Dosing Strategies and DMT Protocol approved. Thereafter Entheon will be able to develop its DMT Products (based on the approved Dosing Strategies and DMT Protocol) and then move through the market authorization regulatory process, following the completing of phase 1, 2 and 3 clinical studies, associated nonclinical studies and preparation of manufacturing documentation. Set forth below is a description of the regulatory regimes in Canada, the United States and the European Union that Entheon is and will be subject to as it moves through both: (i) the clinical study regulatory processes in respect of the Dosing Strategies and DMT Protocol; and the (ii) market authorization regulatory process in respect of the DMT Products.

*Canada – Health Canada*

Clinical Study Regulatory Process

In Canada, a CTA is composed of three modules:

- Module 1 contains administrative and clinical information about the proposed trial, and includes the Investigator's Brochure, which details all safety, preclinical and clinical data for the drug under study. Other components of Module 1 are the clinical study synopsis and full protocol, informed consent documents, clinical trial site information, and letters of access;

- Module 2 contains common technical document summaries, including Chemistry, Manufacturing and Control ("**CMC**") information about the drug product(s) to be used in the proposed trial; and

- Module 3 contains additional supporting quality information including literature references.

The modules are organized and numbered consistently in an internationally adopted format, the Common Technical Document ("**CTD**"). Adhering to the CTD format facilitates evaluation by Health Canada and ensures consistency of documents in subsequent stages of the drug authorization process. Additional documents including a Clinical Trial Site Initiation Form, Qualified Investigator Undertaking and a Research Ethics Board Attestation must be completed for each clinical trial site. Once prepared, the Clinical Trial Application is sent to the Therapeutic Products Directorate at the Health Product and Food Branch ("**HPFB"**) of Health Canada for review. The review process is 30 days, although during the current COVID-19 pandemic environment, Health Canada is able to extend review timelines for non COVID-19 related studies to 45 days.

Health Canada invites sponsors to request a pre-CTA consultation meeting. Such consultations may be particularly useful for new active substances or applications that will include complex issues that may be new to Health Canada. Entheon plans to hold a pre-CTA consultation meeting with Health Canada to discuss proposed phase 2 and 3 efficacy trials for its DMT Products subject to the receipt of any applicable regulatory approvals. The pre-CTA consultation meeting is also subject to the delays and related cost implications discussed under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*".

Market Authorization Regulatory Process

The HPFB is the national authority that regulates, evaluates and monitors the safety, efficacy, and quality of therapeutic and diagnostic products available to Canadians. When a manufacturer decides that it would like to market a drug in Canada, the company must first file a "New Drug Submission" ("**NDS**") with one of the Directorates (e.g. Therapeutic Products Directorate) within the HPFB. The NDS contains information and data about the drug's safety, effectiveness and quality. It includes the results of the preclinical and clinical studies, whether done in Canada or elsewhere, details regarding the production of the drug, packaging and labelling details, and information regarding therapeutic claims and side effects. The HPFB performs a thorough review of the submitted information, sometimes using external consultants and advisory committees. HPFB evaluates the safety, efficacy and quality data to assess the potential benefits and risks of the drug. HPFB reviews the labelling information that the sponsor proposes to provide to health care practitioners and consumers about the drug (e.g. the drug label, product monograph, patient brochure). If, at the completion of the review, the conclusion is that the benefits outweigh the risks and that the risks can be mitigated, the drug is issued a Notice of Compliance, as well as a Drug Identification Number which permits the sponsor to market the drug in Canada and indicates the drug's official approval in Canada. In addition, Health Canada laboratories may test certain biological products before and after authorization to sell in Canada has been issued. This is done through its Lot Release Process, in order to monitor safety, efficacy and quality. This process is predominantly utilized for biologic products seeking a marketing license. Once a drug is on the market, regulatory controls continue. The manufacturer (license holder) and distributors of the drug must report any new information received concerning serious side effects including failure of the drug to produce the desired effect. The manufacturer (license holder) must also notify HPFB about any studies that have provided new safety information and request approval for any major changes to the manufacturing processes, dose regime or recommended uses for the drug. HPFB conducts market surveillance, monitors adverse reaction reports, investigates complaints and problem reports, and manages recalls, should the necessity arise. In addition, HPFB licenses most drug production sites and conducts regular inspections as a condition for licensing.

*United States - FDA*

Clinical Study Regulatory Process

Current United States Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor (which is typically a research and development company or drug manufacturer) will want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The Investigational New Drug Application ("**IND**") is the means through which the sponsor technically obtains this exemption from the FDA. During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. FDA's role in the development of a new drug begins when the drug's sponsor, having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the *Federal Food, Drug, and Cosmetic Act* and becomes a new drug subject to specific requirements of the drug regulatory system.

Entheon plans to submit an IND application as a commercial sponsor. A commercial IND is one for which the sponsor intends to commercialize the product by eventually submitting a marketing application. A physician may also submit a research IND with Entheon's DMT products to propose studying the unapproved drug, or an approved product for a new indication or in a new patient population. A research IND is one for which the sponsor (generally an individual investigator, academic institution or non-profit entity) does not intend to later commercialize the product. These studies are strictly for research, are usually shorter in duration and may result in publications in peer-reviewed journals.

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies, consisting of preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).

- Manufacturing Information, pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This is equivalent to the CMC data referenced above for Health Canada applications, and is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.

- Clinical Protocols and Investigator Information, including detailed protocols for proposed clinical studies to assess whether the initial trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an Institutional Review Board ("**IRB**"), and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

The FDA invites sponsors to request a pre-IND consultation meeting in advance of application submission. This fosters early communications between sponsors and new drug review divisions to provide guidance on the data necessary to warrant IND submission. Entheon plans to hold a pre-IND consultation meeting to discuss proposed phase 2 and phase 3 efficacy trials for its DMT Products, subject to the receipt of any applicable regulatory

approvals. The pre-IND consultation meeting is also subject to the delays and related cost implications discussed under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*".

Market Authorization Regulatory Process

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical products in the United States to ensure that such medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical products manufactured in the United States to international markets and the importation of medical products manufactured abroad. Unless an exemption applies, each new or significantly modified medical product Entheon seeks to commercially distribute in the United States will require FDA approval. The FDA approval process is conducted through the submission of a New Drug Application ("**NDA**"). The process can be expensive, and lengthy (6-12 months), and require payment of significant user fees, unless an exemption is available. Significant reductions in fees are available through the Small Business Fee Waiver/Reduction program. Drug companies seeking to sell a drug in the United States must first test it. The company then sends the Centre for Drug Evaluation and Research ("**CDER**") at the FDA the evidence from these tests to prove the drug is safe and effective for its intended use, using the NDA. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company's data and proposed labeling. If this independent and unbiased review establishes that a drug's health benefits outweigh its known risks, the drug is approved for sale. The center does not actually test drugs itself, although it does conduct limited research in the areas of drug quality, safety, and effectiveness standards. The FDA drug approval process takes place within a structured framework that includes: (i) analysis of the target condition and available treatments; (ii) assessment of benefits and risks from clinical data; and (iii) strategies for managing risks.

In some cases, the approval of a new drug is expedited. Accelerated approval can be applied to promising therapies that treat a serious or life-threatening condition and provide therapeutic benefit over available therapies. The FDA also employs several approaches to encourage the development of certain drugs, especially drugs that may represent the first available treatment for an illness, or ones that have a significant benefit over existing drugs. These approaches, or designations, are meant to address specific needs, and a new drug application may receive more than one designation, if applicable. Each designation helps ensure that therapies for serious conditions are made available to patients as soon as reviewers can conclude that their benefits justify their risks. Designations include: (i) fast track; (ii) breakthrough therapy; and (iii) priority review.

*Europe - EMA*

Clinical Study Regulatory Process

The IMPD is one of several regulatory documents required for conducting a clinical trial of a pharmacologically API (active product ingredient) intended for one or more European Union Member States. The IMPD includes summaries of information related to the quality, manufacture and control of any Investigational Medicinal Product (including reference product and placebo) ("**IMP**"), and data from non-clinical and clinical studies. Guidance concerning IMPDs is based on Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use (the "**Regulation**") and on the approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (also commonly referred to as the "**Clinical Trials Directive**"). The Regulation came into force in 2016, harmonizing the laws, regulations and administrative provisions of the Member States relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. European Member States have transformed the requirements outlined in the Clinical Trials Directive into the respective national laws.

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

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

Entheon is planning the Phase I Study to obtain preliminary evidence of the safety and efficacy of infused DMT. The study is expected occur in the Netherlands in late 2021. The Company has prepared an Investigator's Brochure (including prior safety, preclinical and clinical data), and is currently preparing an IMPD document that includes CMC (Chemistry, Manufacturing and Control) information and a clinical study protocol and supporting information. The Investigator's Brochure has already been submitted to the CCMO, and the IMPD and clinical protocol are expected to Dutch regulatory authorities be submitted in 2021, subject to the risks, delays and related cost implications discussed under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*".

Market Authorization Regulatory Process

Under the centralized authorization procedure, pharmaceutical companies submit a single marketing-authorization application to the EMA, which provides the basis of a legally binding recommendation that will be provided by the EMA to the European Commission, the authorizing body for all centrally authorized products. This allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the European Union on the basis of a single marketing authorization. EMA's Committee for Medicinal products for Human Use or Committee for Medicinal Products for Veterinary Use carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not, under any particular dosing regime. Although, under European Union law, the EMA has no authority to permit marketing in the different European Union countries, the European Commission is the authorizing body for all centrally authorized products, who takes a legally binding decision based on EMA's recommendation. This decision is issued within 67 days of receipt of EMA's recommendation. Once granted by the European Commission, the centralized marketing authorization is valid in all European Union Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. European Commission decisions are published in the Community Register of medicinal products for human use. Once a medicine has been authorized for use in the European Union, the EMA and the European Union Member States constantly monitor its safety and take action if new information indicates that the medicine is no longer as safe and effective as previously thought. The safety monitoring of medicines involves a number of routine activities ranging from: assessing the way risks associated with a medicine will be managed and monitored once it is authorized; continuously monitoring suspected side effects reported by patients and healthcare professionals, identified in new clinical studies or reported in scientific publications; regularly assessing reports submitted by Entheon holding the marketing authorization on the benefit-risk balance of a medicine in real life; and assessing

the design and results of post-authorization safety studies which were required at the time of authorization. The EMA can also carry out a review of a medicine or a class of medicines upon request of a Member State or the European Commission. These are called European Union referral procedures; they are usually triggered by concerns in relation to a medicine's safety, the effectiveness of risk minimization measures or the benefit-risk balance of the medicine. The EMA has a dedicated committee responsible for assessing and monitoring the safety of medicines, the Pharmacovigilance Risk Assessment Committee. This ensures that EMA and the European Union Member States can move very quickly once an issue is detected and take any necessary action, such as amending the information available to patients and healthcare professionals, restricting use or suspending a medicine, in a timely manner in order to protect patients.

**Production and Services**

Entheon is not, and does not intend, to produce the DMT that it will utilize in the DMT Products and in the pre-clinical and clinical studies leading up to commercialization. As discussed in further detail above under the heading "*Description of the Business – Summary – Timing and Stage of Research and Development,*" Entheon has entered into supply agreements with two chemical manufacturing organizations, Psygen Labs in Alberta, Canada, and Ofichem B.V. in the Netherlands. These manufacturers will provide Entheon with the Drug Products (GMP quality and non-GMP DMT drug products and substances) for its preclinical, clinical and post-approval commercialization phases. Under the Psygen Supply Agreement, Entheon is obliged to pay to Psygen an aggregate of USD$40,000 for the initial supply purchase order of the Drug Products to be used for the Phase I Study. Within the timeframes specified in the Psygen Supply Agreement, the parties shall negotiate the purchase price and the break fee for all other clinical trial phases to follow. In each case, the purchase price shall be increased based on reasonable good-faith negotiation by the parties. Under the Ofichem Services Agreement, Entheon has agreed to pay Ofichem an aggregate of €98,520 in exchange for Ofichem synthesizing, validating and producing GMP quality DMT for use as a secondary source in clinical phase I studies. In the long term should Entheon be in a position to commercialize its DMT Products, it expects to enter into manufacturing agreements with third parties to manufacture the DMT Products.

Additionally, Entheon intends to contract with manufacturers to develop the DMT Delivery System described in further details above under the heading "*Description of the Business – Summary – DMT Delivery System.*" The DMT Delivery System will incorporate the specific inputs and design requirements derived from Entheon's Preclinical Studies, the Phase I Study and any further clinical trials conducted thereafter. In the development of the DMT Delivery System, Entheon expects to use existing approved infusion pump systems ("**IPS**") similar to those found in anaesthetics and patient-controlled analgesia kits from companies like Becton, Dickinson and Company (United States), B. Braun Melsungen AG (Germany), and Baxter International Inc. (United States). The IPS will enable Entheon to provide controlled, consistent and continuous drug delivery of Entheon's DMT Products.

**Specialized Skills and Knowledge**

Pursuant to certain consultant agreements, in order to assist in the development of its DMT Solutions and the DMT Protocol, Entheon has retained, on an exclusively advisory basis, a number of arm's length Science Advisors, with specialized skills and knowledge and extensive experience in the field of neuropharmacology, genetics, psychiatry and substance use disorders. With proven track records in drug development, biotechnology research and psychedelic medicine, the Science Advisors are considered valuable assets to Entheon's business. Set forth below is a brief description of the relevant background and experience of each of the Science Advisors:

- **Michael Walker, Ph.D**. - Dr. Walker received his pharmacology training at the University of London which included a period of drug discovery training at Pfizer Ltd., (UK). His main focus has been in the

discovery of drugs, whether naturally occurring or not, and in the process of drug discovery itself. His commitment to his industry includes 43 years at the University of British Columbia and numerous contributions to universities around the world. Over the past 25 years, Dr. Walker was the founder or co-founder of eight different drug discovery companies, both public and private, including Cardiome (now Correvio) Pharma in Canada and Verona Pharma in London, UK. Additionally, Dr. Walker has researched and published numerous journals, periodicals, conference presentations, and other related publications. Dr. Walker has executed an advisory board member consulting agreement dated January 15, 2020 for an initial term of one year, to be renewed for successive one year terms, which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of $2,000 monthly.

- **Yaron Eshel** - Mr. Eshel has 15 years of experience in life sciences innovation. He has led efforts in development, regulatory compliance, and operations. Mr. Eshel has worked within start-ups as well as consulted for them. Mr. Eshel has navigated the United States, European Union, Israeli and Australian regulatory agencies including the registration of manufacturing facilities in the United States, Central America, Israel and Australia to Good Manufacturing Practice levels. Yaron has led clinical trials in the United States, the European Union and Israel as well as worked with CRO's all over the world. Mr. Eshel is a graduate of University of New South Wales with a BSc in Organizational Psychology and Philosophy of Science, and holds an Executive Masters of Business Administration from MacQuarie Graduate School of Management. Mr. Eshel has executed a consulting agreement through his company Next Step Consulting dated October 1, 2019 for an initial term of one year, which among other things, contains non-competition provisions. Compensation under the agreement includes a fee of $2,750 monthly.

- **Christopher Gondi, Ph.D.** - Dr. Gondi is a Research Assistant Professor - Departments of Medicine, Surgery and Pathology at the University of Illinois College of Medicine Peoria. He is a professor of cancer biology and has extensive experience dealing with brain tumors and pancreatic cancer, for which the survival rates are very low. His passion for psychedelics is bred of his duty of care for patients during and after treatment of their cancer, whether the treatments fail or succeed. Dr. Gondi has executed an independent director agreement commencing on August 9, 2019 and terminating on the earlier of (i) the date of Entheon's next annual general meeting of shareholders; and (ii) the earlier of the following to occur: (A) the death of Dr. Gondi; (B) the termination of Dr. Gondi from the Board by the mutual agreement of Entheon and Dr. Gondi; (C) the removal of Dr. Gondi from the Board by the shareholders of Entheon in the manner prescribed by the CBCA; and (D) the resignation by Dr. Gondi from the Board. The agreement which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of $3,000 per fiscal quarter.

- **Matthew W. Johnson, Ph.D.** - Dr. Johnson is a Professor of Psychiatry and Behavioral Sciences at Johns Hopkins University, and an expert on psychoactive drugs and addiction. He is one of the world's most widely published scientists on the human effects of psychedelics. Dr. Johnson earned his Ph.D. in experimental psychology at the University of Vermont in 2004, and has published over 110 peer-reviewed articles. Working with psychedelics for 16 years, Dr. Johnson published psychedelic safety guidelines in 2008, helping to resurrect psychedelic research. He published the first research on psychedelic treatment of tobacco addiction in 2014, and the largest study of psilocybin in treating cancer distress in 2016. His 2018 psilocybin abuse liability review recommended placement in Schedule-IV upon potential medical approval. Dr. Johnson is also known for his research in behavioral economics, including decision making underlying addiction, tobacco regulatory science, and drug effects on sexual risk behavior. He has published studies on nearly all psychoactive drug classes. Dr. Johnson was the 2019 President of the Psychopharmacology and Substance Abuse Division of the American Psychological Association, and is the current President of the International Society for Research on Psychedelics. He has received continuous funding as principal investigator for over 12 years. Dr. Johnson has reviewed for over 75 scientific journals, and reviewed grants for the National Institutes of Health, National Science

Foundation, the United States Military, and multiple governments outside of the United States. He has provided invited presentations of his research in 13 nations. Dr. Johnson has executed an advisory services agreement dated October 21, 2019 for an initial term of one year, to be renewed for successive one year terms, which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of USD$5,500.

- **Robin Carhart-Harris, Ph.D.** - Dr. Carhart-Harris Heads the Psychedelic Research Group within the Centre for Psychiatry at Imperial College London, where he has designed a number of functional brain imaging studies with psilocybin (magic mushrooms), LSD, MDMA (ecstasy) and DMT, plus a clinical trial of psilocybin for treatment resistant depression. He has over 50 published papers in peer-reviewed scientific journals; two of which were ranked in the top 100 most impactful academic articles of 2016. Dr. Carhart-Harris obtained his Ph.D. in Psychopharmacology from the University of Bristol, and prior to that, a M.A. in Psychoanalysis at Brunel University. He has an honorary position at the University of Oxford. Dr. Carhart-Harris has executed an advisory services agreement dated January 7, 2020 for an initial term of one year, to be renewed for successive one-year terms, which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of GBP£3,600 per fiscal quarter.

- **Christopher Timmermann, Ph.D.** - Dr. Timmermann is a psychologist educated at the Catholic University of Chile with a Masters in Neuroscience and Neuropsychological Therapy from the University of Bologna, and received his Ph.D. at the Centre for Psychedelic Research at the Imperial College of London. His research focuses on the effects of DMT in the human brain. Dr. Timmermann has executed an advisory board member consulting agreement dated January 20, 2020 for an initial term of one year, to be renewed for successive one year terms, which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of GBP£1,200 per fiscal quarter.

- **Malin Vedøy Uthaug, Ph.D.** - After completing her Ph.D. at the department of Neuropsychology and Psychopharmacology, at the faculty of Psychology and Neuroscience at Maastricht University, the Netherlands, Dr. Uthaug investigated the short-term and long-term effects of Ayahuasca and 5-MeO-DMT in naturalistic settings, while simultaneously initiating several other studies on the psychedelic substance mescaline and the breathing practice known as Holotropic Breathwork (HB). Dr. Uthaug is currently working as a Research Assistant at The Centre for Psychedelic Research, at Imperial College London, led by Dr. Robin Carhart-Harris. Here she is investigating the effects of 5-MeO-DMT on mental health related variables, brain activity and consciousness together with Christopher Timmermann, Ph.D. candidate. Besides being a researcher investigating psychedelics as a novel treatment option for mood-related disorders and trauma, Dr. Uthaug is also an editor for the “Journal of Psychedelics Studies”, a board member of the American podcast-show known as “Psychedelics Today”, and the co-founder of the Norwegian Association for Psychedelic Science (Norsk Forening for Psykedelisk Vitenskap) whose main aim is to educate the general public as well as researchers, and mental health practitioners in Norway about psychedelics. Dr. Uthaug has executed an advisory services agreement dated May 22, 2020 for an initial term of one year, to be renewed for successive one year terms, which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of GBP£1,200 per fiscal quarter.

- **Nancy Maher -** A global IT leader with significant experience in utilizing and enabling technology to deliver efficiency, productivity, quality and solutions for patients and the public health sector, Ms. Maher has an extensive background in digital technology, big data and data analytics, as well as M&As. With more than 20 years of industry experience, including significant leadership roles at Gilead, Allergan, Teva, Merck, Schering-Plough, and IBM, Ms. Maher currently serves as Senior Vice-President, Chief Information Officer of Kyowa Kiran NA, where she is establishing the company's global digital and

technology strategy. Ms. Maher has executed an advisory consulting agreement dated February 22, 2021 for an initial term of one year.

- **Dr. Dinesh Bhayana, MD –** Dr. Bhayana is an emergency and addiction medicine physician based in Toronto, ON, Canada. He completed medical school at the University of Western Ontario and residency at the University of Toronto. Since 2013, he has worked in both hospital and community settings in Northern Ontario and Toronto, caring for patients dealing with the entire spectrum of substance use disorders. He has extended training and experience in Ketamine-Assisted Psychotherapy and serves as a director on the board of MAPS (Multidisciplinary Association for Psychedelic Studies) Canada. Dr. Bhayana has executed an advisory services agreement dated June 1, 2021 for an initial term of two years, to be renewed for successive one year terms, which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of $3,000 per fiscal quarter to commence six months from the agreement date.

**Competitive Conditions**

The following is a discussion of the trends, market outlook and competitive conditions related to Entheon's business. Subject to receiving the applicable FDA, Health Canada and EMA approvals, Entheon intends to operate in the United States, Canada and different countries in the European Union.

***Trends***

Substance-use disorder is a prominent fixture in modern society and takes the lives of many each year. Though current treatments exist such as medication assisted therapies, psychotherapy, and abstinence, thousands of people continue to lose their lives to a variety of substance use disorders.

Recently, there has been a resurgent interest in psychedelics as a potential treatment for a variety of psychiatric disorders including depression, post-traumatic stress disorder, and substance use disorder. When administered safely and in an appropriate environment, with adequate support, certain psychedelic-assisted psychotherapies may assist in treating substance use disorders.

Some of the more well-known companies exploring the use of psychedelics in the treatment of mental health disorders include: (i) Mind Medicine (MindMed) Inc., (ii) Compass Pathways Limited, (iii) Small Pharma and (iv) Eleusis Ltd., each of which are described in further detail below.

***Market Outlook***

Entheon intends to operate and market the DMT Solutions within Canada, the United States and throughout the European Union. Psychedelics are not widely available as legal forms of medical treatment within Canada and the United States, though there are many unregulated practitioners. If psychedelic drugs are approved for sale by Health Canada and the FDA, doctors will be able to prescribe them as they would other drugs. Nonetheless, there are currently clinics within Canada and the United States that provide doctor prescribed ketamine (another psychedelic drug) treatments. Within Canada specifically, Actify Neurotherapies, Field Trip Health and others provide doctor prescribed ketamine therapies in controlled settings.

Based on the following statistics, psychedelic-assisted therapies may emerge in the foregoing jurisdictions as an important tool for treating substance use disorders where other treatment types have failed.

- In 2018 there were an estimated 14.4 million adults in the United States who had alcohol use disorder[1], and according to the National Survey on Drug Use and Health, an estimated 88,000 people die in the United States from alcohol-related causes annually[2] (the 3rd leading preventable cause of death in the United States), while globally 3.3 million deaths, or 5.9 percent of all global deaths, were attributed to alcohol consumption[3].

- The total cost of alcohol-related harm to Canadians was estimated to $14.6 billion in 2014, and a comprehensive study completed in 2010 concluded that alcohol misuse in the United States had an economic and financial toll of $249.0 billion[4].

- In 2017, an estimated 20.7 million people aged 12 or older needed substance use treatment (i.e., treatment for problems related to the use of alcohol or illicit drugs), yet in the same year only approximately 4.0 million of those people had received any substance use treatment in the past year[5], highlighting a major deficit between need and access.

- Globally, only half of countries provide access to effective treatment options for opioid dependence and it is estimated that less than 10% of people worldwide who are in need of treatment actually receive it[6]. According to The National Institute on Drug Abuse, approximately 2.1 million Americans have a prescription opioid-use disorder, while overdose deaths are five times higher in 2016 than they were in 1999[7]. *The Global Burden of Diseases, Injuries, and Risk Factors Study* concluded with an estimation that in 2017, 40.5 million people were opioid dependent, and that in that same year 109,500 people had died from an opioid overdose[8].

- The Canadian Centre for Substance Abuse and Addiction found that in 2017, "substance use cost Canadians almost $46.0 billion, led to over 275,000 hospitalizations and contributed to the loss of nearly 75,000 lives in Canada". Of this, opioid substance-use resulted in estimated costs (healthcare, lost productivity, criminal justice costs and other direct costs) of $5.9 billion[9], while in the United States, the Center for Disease Control & Prevention estimates that the "economic burden" of prescription opioid misuse alone is $78.5 billion a year[10].

- The Center for Disease Control & Prevention reports that more than 16 million people in the United States are living with a disease that has been linked to smoking[11], and 480,000 annual deaths are

[1] National Institute on Alcohol Abuse and Alcoholism.
[2] Centers for Disease Control and Prevention (CDC). *Alcohol and Public Health: Alcohol-Related Disease Impact (ARDI). Average for United States 2006–2010 Alcohol-Attributable Deaths Due to Excessive Alcohol Use*.
[3] World Health Organization (WHO). *Global Status Report on Alcohol and Health.* p. XIV. 2014 ed.
[4] Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; et al. 2010 national and state costs of excessive alcohol consumption. *American Journal of Preventive Medicine* 49(5):e73–e79, 2015. PMID: 26477807.
[5] Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health, pg.50.
[6] https://www.who.int/news-room/fact-sheets/detail/opioid-overdose.
[7] *Medications to Treat Opioid Use Disorder Research Report*. National Institute on Drug Abuse. Research report, Revised June 2018.
[8] *Global patterns of opioid use and dependence: harms to populations, interventions, and future action.* The Lancet, VOLUME 394, ISSUE 10208, P1560-1579, OCTOBER 26, 2019.
[9] Canadian Substance Use Costs and Harms Scientific Working Group (2020). Canadian substance use costs and harms 2015–2017. (Prepared by the Canadian Institute for Substance Use Research and the Canadian Centre on Substance Use and Addiction.) Ottawa, Ont: Canadian Centre on Substance Use and Addiction.
[10] Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Med Care. 2016;54(10):901-906.
[11] https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/

"caused" by smoking[12]. The World Health Organization believes the global financial burden imposed by cigarette consumption and addiction to be well over one trillion dollars[13].

This combination of an under-serviced population of substance use disorder sufferers for whom there are limited treatment options, paired with the low efficacy of said treatment options may or may not result in amendments to the current legislation surrounding the use of psychedelic-assisted therapies. While no such changes to legislation have occurred to date, psychedelics as therapies are in various states of legality. Recently the Canadian Federal Government made a decision, allowing four terminal cancer patients to legally use psilocybin (another psychedelic drug) to relieve their end-of-life anxiety through medical exemption[14]. Since then, Health Canada has approved 24 more applications from cancer patients for treatment of end-of-life distress. It has also granted exemptions to 19 health-care providers, giving them the right to possess and use mushrooms containing psilocybin for professional training purposes[15]. In the United States, the results of several psychedelic therapy clinical trials are currently being put forth to the FDA by companies seeking regulatory approval to ultimately sell prescribed psychedelic therapies for medical consumer use. For example: (i) the Multidisciplinary Association for Psychedelic Studies is in phase 3 of clinical trials of methylenedioxy methamphetamine (otherwise known as "MDMA", another psychedelic drug) to treat post-traumatic stress disorder[16][17]; and (iii) the Usona Institute is in a phase 2 study focusing on the use of psilocybin for major depressive disorder.[18]

Additionally, other psychedelic therapies such as esketamine or Spravato (versions of the previously banned substance ketamine) have been approved and are currently being prescribed for medical use[19]. Notwithstanding the foregoing, the use of psychedelic-assisted therapies, and DMT in particular, may never become legal. As such, there is no guarantee that Entheon will be able to commercialize its DMT Products; additionally, the legislation surrounding the use of psychedelic-assisted therapies may be amended in unanticipated ways, which also may prevent Entheon from being able to commercialize its DMT Products or which may require the need to raise additional capital. All of the foregoing uncertainties may have timing and cost implications on Entheon's business plans and strategies. Certain regions in the United States have decriminalized psychedelics such as Denver's Initiative 301 ballot which decriminalized psilocybin mushroom possession. Oakland and Santa Cruz, California have also decriminalized psychedelic possession. Washington DC also submitted a decriminalization initiative (Initiative 81), which was approved by voters on November 3, 2020.[20]

***Competition***

Entheon is the only DMT-focused company targeting addiction. At the time of filing, no other company has filed addiction-specific patent applications surrounding DMT, or have proposed clinical trials with respect to DMT and addiction. While other companies exist that are utilizing DMT as their intended molecule, no competitor has expressed an interest in pursuing DMT to treat addiction. However, there are several other companies pursuing both: (a) research and development targeting addiction utilizing other psychedelic inspired medications, and (b) DMT in the treatment of other mental health conditions. Set forth below are Entheon's largest competitors.

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[12] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

[13] https://www.who.int/tobacco/economics/background/en/.

[14]https://therapsil.ca/in-a-landmark-decision-canada-allows-4-terminal-patients-to-legally-use-psilocybin-to-ease-anxiety/

[15] https://www.ctvnews.ca/health/patient-hopes-canada-will-introduce-regulations-for-treatment-with-magic-mushrooms-1.5270875

[16] https://clinicaltrials.gov/ct2/show/NCT03537014

[17] https://clinicaltrials.gov/ct2/show/NCT03775200

[18] https://clinicaltrials.gov/ct2/show/NCT03866174

[19] https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified

[20] https://ballotpedia.org/Washington,_D.C.,_Initiative_81,_Entheogenic_Plants_and_Fungus_Measure_(2020).

- **Mind Medicine (MindMed) Inc.** – is a New York based company listed on the NEO Exchange and the OTC Market that is exploring the use of Ibogaine and microdoses of lysergic acid diethylamide (otherwise known as "LSD", a hallucinogenic drug) in the treatment of opioid use disorder, cluster headaches, anxiety and adult attention deficit hyperactivity disorder. While also a biotechnology research and development company, MindMed is focused on treating a wide variety of physical and mental disorders, whereas Entheon is exclusively focused, and using all of its resources, on only treating addiction and substance use disorders.

- **Compass Pathways Limited** – is a United Kingdom based public mental health care company trading on Nasdaq, dedicated to accelerating patient access to evidence-based innovation in mental health. The company, like Entheon, is focused on the clinical trial pathway, but is tackling treatment resistant depression and studying psilocybin. The company received "Breakthrough Therapy" designation from the FDA in 2018 and is presently conducting randomized controlled phase 2 studies[21] of psilocybin therapy, testing safety and efficacy of psilocybin in participants with treatment resistant depression[22].

- **Small Pharma** – is a United Kingdom based public company trading on the TSX Venture Exchange, focused on creating novel psychedelic formulations for the treatment of clinical depression. The company, at present, is researching DMT, and deuterated forms of DMT as molecules, but is focusing its efforts on treating a separate indication, being clinical depression.

- **Eleusis Ltd.** – is a clinical stage life science private company based in New York and London that is dedicated to unlocking the therapeutic potential of serotonin 2A receptor agonists, through the mitigation and management of psychoactivity. The company, like Entheon, is focused on the clinical trial pathway, but is utilizing a different psychedelic molecule being LSD.

**Components**

As discussed in further detail above under the heading "*Description of the Business – Summary – Timing and Stage of Research and Development,*" Entheon has entered into supply agreements with Psygen Labs (Alberta, Canada) and Ofichem B.V. (Netherlands). Ofichem has been contracted by Entheon to produce GMP-quality DMT as a secondary source of material for the Phase I Study at a cost of EUR 98,520.

**Intangible Properties**

***Patents***

In connection with the Dosing Strategies and the DMT Delivery System, Entheon has filed four provisional patent applications under the Licensed Patent Rights with the United States Patent and Trademark Office.

- The first provisional patent was filed on October 22, 2019 and is focused on the treatment and management of addiction. This patent relates to a variety of molecular compositions including DMT and Ayahuasca which allow for the improved use of psychedelics at both a hallucinogenic and sub-hallucinogenic level to combat addiction. Ayahuasca is a brew composed of a psychedelic tryptamine and beta carbolines (another chemical compound) with monoamine oxidase inhibitors, (best known as antidepressants). Ayahuasca exerts anti-addictive properties via its direct and indirect effects on the dopaminergic and serotonergic neurons in the mesolimbic pathway (a brain pathway that is thought to

[21] Where a phase 1 trial emphasizes safety, phase 2 trials focus on effectiveness, aiming to obtain preliminary data on whether the drug works in people with specific diseases or conditions. Phase 3 trials continue to study safety (i.e. short term side effects) and can last up to several years.
[22] https://clinicaltrials.gov/ct2/show/NCT03775200.

involve cognitive control, motivation, and emotional responses). The combination of DMT and beta carbolines prolongs the half-life of DMT.

- The second provisional patent application was filed on July 7, 2020 and is focused on psychedelic-assisted therapy for the treatment of nicotine addiction. DMT is rapidly metabolized in the body, making it a flexible therapeutic alternative to other serotonergic hallucinogens which can have effects lasting 12 hours or longer. However, the fast onset and intensity of DMT's effects can be overwhelming, particularly in patients with no prior experience with psychedelic drugs. Entheon's second provisional patent relates to a treatment protocol that slowly titrates DMT into the body using methods based on target-controlled intravenous infusion technology. This patent was refiled on March 11, 2021.

- The third provisional patent application was filed on August 13, 2020 and is focused on psychedelic-assisted therapy for the treatment of alcohol addiction, using the DMT Delivery System described above for treating nicotine addiction. This patent was refiled on March 11, 2021.

- The fourth provisional patent application was filed on September 4, 2020, and is focused on psychedelic-assisted therapy for the treatment of opiate addiction, using the DMT Delivery System described above for treating nicotine addiction. This patent was refiled on March 11, 2021.

Entheon intends to file additional patent applications specific to substance use disorder administration methods and dosage strategies and to its DMT Delivery System. If approved, patented administration methods, dosage strategies, protocols and DMT Delivery System will be marketed initially in the European Union, Canada and the United States pending the receipt of all applicable regulatory approvals.

**Economic Dependence**

Set forth below is a summary of the two arm's-length material contracts that Entheon has entered into as of the date hereof, on which the Company's business is substantially dependent.

- **Psygen Supply Agreement**. Entheon has entered into the Psygen Supply Agreement whereby Psygen will provide Entheon with GMP and non-GMP quality DMT drug products and substances (the "**Drug Products**") for its preclinical, clinical and post-approval commercialization phases under the European regulatory framework. Psygen is located in Alberta, Canada and is licensed by the Health Canada Office of Controlled Substances to manufacture, sell and export DMT. The Psygen Supply Agreement is governed by the laws of the province of Alberta and the laws of Canada applicable therein. The Psygen Supply Agreement expires upon the latter of (i) ten years from the effective date of the Psygen Supply Agreement; and (ii) completion of the Study (as defined in the Psygen Supply Agreement), unless otherwise terminated by either party in accordance with Article 15 of the Psygen Supply Agreement, provided that the term will continue to apply as necessary in respect of outstanding payments owed in accordance with the Psygen Supply Agreement. The term of the Psygen Supply Agreement will automatically be extended for one additional period of five years unless either Psygen or Entheon provides notice in writing that it has elected not to extend the term at least six months prior to the end of the term. Under the Psygen Supply Agreement, as set forth in the table below, Entheon is obliged to pay to Psygen an aggregate of USD$40,000 for the initial supply purchase order of the Drug Products to be used for the Phase I Study. Within the timeframes specified in the Psygen Supply Agreement, the parties shall negotiate the purchase price and the break fee for all other clinical trial phases to follow. In each case, the purchase price shall be increased based on reasonable good-faith negotiation by the parties. As of the date hereof no payments have been made under the Psygen Supply Agreement.

| Item | Form / Strength | Unit Size | Units | USD$ / Unit | USD$ Total |
|---|---|---|---|---|---|
| DMT fumarate (GMP) (1) | Active Pharmaceutical Ingredient | g (bulk) | 50 | 750 | $37,500 |
| DMT fumarate (Non-GMP) (2) | Active Pharmaceutical Ingredient | g (bulk) | 5 | 500 | $2,500 |
| **Total Purchase Price for this Purchase Order** | | | | | **USD$40,000** |

(1) DMT fumarate is a water soluble salt of DMT that allows it to be easily dissolved in saline solution for intravenous use. GMP refers to the drug produced at high purity according to international Good Manufacturing Practices and is required for human use.

(2) Non-GMP is produced in a less stringent way and intended as a "research batch" for animal or laboratory use only.

- **Ofichem Services Agreement.** Entheon has contracted Ofichem B.V., located in Ter Apel, Netherlands, to produce GMP-quality DMT substance, as a secondary source of material for the Phase I Study. Ofichem is licensed in the Netherlands to produced GMP-quality DMT, and has existing relationships with both the Centre for Human Drug Research and the Leiden University Medical Centre. Under the Ofichem Services Agreement, Entheon has agreed to pay Ofichem an aggregate of €98,520 in exchange for Ofichem synthesizing, validating and producing GMP quality DMT for use in the Phase I Study. Each of Entheon and Ofichem may terminate the agreement upon delivering notice to the other party.

- **CHDR Clinical Study Agreement.** Entheon has entered into the CHDR Clinical Study Agreement with CHDR (the Centre for Human Drug Research located in Leiden, Netherlands) to perform a DMT-based phase I safety and proof-of-concept clinical study in humans (the "**Phase I Study**"), as discussed in further details under the heading "*Research and Development Studies*." CHDR holds the requisite regulatory approvals under the UN71 (and the other applicable EU conventions – discussed in further detail under the heading "*Regulatory Regimes and Foreign Operations – Regulatory Approvals Required for Studies – Europe*") necessary to conduct the Phase I Study. The Phase I Study is now expected to take place in the Netherlands in late 2021, subject to delays that may result from the on-going COVID-19 pandemic and the related responses of the Canadian and Dutch government and the affect that COVID-19 may have on the global economy, CHDR and Entheon's financial condition, operations and personnel, the health and safety of trial subjects and general travel and mobility permissions. Pursuant to the CHDR Clinical Study Agreement, Entheon has agreed to: (i) pay CHDR an estimated fee of €927,314 for completion of the Phase I Study; and (ii) supply CHDR with DMT to be used in the Phase I Study free of charge and within the timeframe and in the quantities set forth in the agreement. Unless terminated earlier, the term of the CHDR Clinical Study Agreement will continue for the duration of the Phase I Study and may be extended by mutual written agreement of the parties. As of the date hereof, no payments have been made under the CHDR Clinical Study Agreement.

As explained above, each of Psygen and CHDR hold the necessary regulatory licenses and approvals required to possess and handle DMT as provided in the Psygen Supply Agreement and the CHDR Clinical Study Agreement. In connection with these agreements, Entheon intends to have the DMT delivered directly from Psygen to CHDR, such that Entheon will never directly take possession of or handle the DMT and will therefore not be required to possess the regulatory licenses and approvals applicable thereto.

**Changes to Contracts**

Entheon does not anticipate its business will be affected by renegotiation or termination of contracts or subcontracts during the current financial year. In the unlikely event that the Psygen Agreement is terminated,

Entheon may be forced to find alternative suppliers, a process which may delay commencement of the clinical trial at CHDR.

**Employees**

Entheon has 4 full-time employees and 20 consultants and part-time contractors.

**Foreign Operations**

At this stage Entheon's business is dependent on foreign operations only to the extent that it conducts preclinical and clinical studies in the United States and the EU. Currently, Entheon only has clinical trials scheduled to take place in the Netherlands. Entheon's business will be further subject to foreign operations when it eventually begins selling its DMT Products and licensing the DMT Delivery System in the United States and the EU, as intended. Entheon has chosen to conduct its initial clinical trials in the Netherlands due to both: (i) the existence of a longstanding and strategic relationship between its clinical advisors and CHDR (the Center for Human Drug Research), and (ii) CHDR's reputation as a world-class early stage clinical research organization with a proven track record of quality and efficiency. Management of Entheon believe that taking this route will allow Entheon to competitively capitalize on both the insight and goodwill that such a strategic relationship brings, along with the knowledge and experience CHDR has in going through the regulatory approval process in Europe. Subject to the any risks, delays and related cost implications resulting from COVID-19 (discussed further under the heading "*General Development of the Business – Business Outlook for the Upcoming Year*"), Entheon intends to rapidly move forward in the EU regulatory approval process for its nicotine secession indication while simultaneously pursuing phase 2 clinical trial approvals in Canada and the United States. Although the completion of clinical trials in the Netherlands will not directly support market approval applications in the United States and Canada, a successful outcome in well-designed safety studies may be one of the factors considered by regulators in these other North American jurisdictions. As described above under the heading "*Description of the Business – Regulations*", Entheon intends to engage Health Canada and FDA to identify the most efficient path toward trial approval. See "*Risk Factors – Risks Relating to the Business - Risks of Operating in European Countries*" for more information on the risks relating to operating in foreign countries to which the Company is subject.

**Other Business Activities**

***EEG Project Expansion***

Entheon is actively developing electroencephalograph ("**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, 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. The estimated cost is between $400,000 and $1,000,000.

***Digital Experience Development***

Entheon is developing VR and AR based digital products to aid in the psychedelic-assisted psychotherapy preparation, treatment, and integration process. Entheon will research the extent to which VR programs, when paired with specified audio production and neuro-technology, can affect and expand a patient's experience to prepare for and benefit from therapeutic interventions. Entheon has hired Jonna Birgans, an experienced media producer, as VP of Digital Experiences to manage and lead the development of this project. Entheon is working with Dash Radio in the creation of VR "multiverses" and a catalogue of experiences to aid and assist the preparatory phase of treatment as well as the post-therapy phase of treatment. VR is intended to acclimate people to the psychedelic experience and presents a platform for the integration of specifically engineered audio and visual productions in to a psychotherapeutic program. The Fully Integrated Digital Experience is intended for eventual use in Entheon's DMT-based protocols, and is intended for near-term expansion across other molecules and treatment modalities. The estimated cost is between $400,000 and $2,000,000.

***EEG & Ketamine R&D – Further investment into Heading Health***

Having already participated in a Series A Preferred Stock Financing, investing $200,000 USD for a 5% stake in Heading Health, Entheon intends to increasing its stake in Heading Health to 10% ownership, providing R&D implications to Entheon, including increased exposure to the ketamine-assisted therapy space and the gathering of raw patient data in order to inform our 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.

This business arrangement enables Entheon to access 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 patient experience.

Entheon will implement EEG technology within Heading Health clinics to measure brain activity before, during and after treatments. This data will be leveraged to aid in the development of Entheon's EEG platform, with a particular focus on gaining insights into specific patient phenotypes leading to valuable insights about the patient experience and how to best tailor and conduct therapy moving in to the future.

Heading Health will provide guidance regarding clinical practice and the use of biomarker capture devices both in general psychiatric practice and Ketamine treatments.

Entheon is pursuing a research agreement with Heading Health with the objective of evaluating the effects of ketamine in order to better characterize this compound in the context of therapeutic application. Entheon will sponsor the studies, which will initially be an observational, open label-controlled study and will include 45 participants. The estimated cost is between $400,000 and $750,000.

***Commercial Expansion of Halugen***

On January 14, 2021, Entheon acquired HaluGen, a biotech company in the business of developing and commercializing a pre-screening test to identify genetic markers predictive of an individual's reaction to hallucinogenic drugs, the "Psychedelics Genetic Test". In tandem with Entheon management, HaluGen has since completed all research, development, and pre-commercialization objectives and has launched the Psychedelics Genetic Test to the general public for purchase through their online platform.

HaluGen's genetic test will improve the tools available to screen patients for underlying psychiatric disorders prior to undertaking psychedelic assisted therapy. Having completed the creation of the Genetic Test and the Technology Platform, HaluGen completed the steps needed to commercialize the Pre-Screening Test for steady state operations.

Entheon seeks to expand HaluGen's commercial reach via expansion of its sales and marketing efforts digitally and B2B.

Entheon seeks to further develop its genetics capacities and intends to expand HaluGen's genetic biomarkers to be more broadly focussed on mental health to investigate what comprised certain mental health diagnoses for possible development into new genetics products as well to feed Entheon's larger data gathering endeavours. The estimated cost is between $300,000 and $1,000,000.

## RISK FACTORS

There are a number of risk factors that could cause future results to differ materially from those described herein. The following are certain risk factors relating to the business carried on by the Company, which prospective investors should carefully consider before deciding whether to purchase Entheon Shares. The risks and uncertainties described herein are not the only ones that the Company faces. Additional risks and uncertainties, including those that the Company does not know about now or that it currently deems immaterial, may also adversely affect the Company's business. If any of the following risks actually occur, the Company's business may be harmed and its financial condition and results of operation may suffer significantly. References to the Company include its owned and partially-owned subsidiaries and affiliates in which the Company has an interest, as applicable.

### Risk Relating to the Entheon Shares

***Market for securities and volatility of share price***

There can be no assurance that an active trading market in Entheon's securities will be sustained. The market price for Entheon's securities could be subject to wide fluctuations. Factors such as government regulation, interest rates, share price movements of peer companies and competitors, announcements of quarterly variations in operating results, revenues and costs, and sentiments toward stocks as well as overall market movements, may have a significant adverse impact on the market price of the securities of Entheon. The stock market has from time to time experienced extreme price and volume fluctuations, which have often been unrelated to the operating performance of a particular company.

***Speculative nature of investment risk***

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

***Need for additional financing and possible effects of dilution***

Entheon may issue equity securities to finance its activities, including future acquisitions. If Entheon were to issue additional Entheon Shares, existing holders of such Entheon Shares may experience dilution in their holdings. Moreover, when Entheon's intention to issue additional equity securities becomes publicly known, the price of the Entheon Shares may be adversely affected.

***Dividends***

Entheon has not paid any dividends on the outstanding Entheon Shares, nor is there any intention of paying dividends in the foreseeable future. Any decision to pay dividends on the Entheon Shares will be made by the Board on the basis of its earnings, financial requirements and other conditions.

**Risks Relating to the Business**

***Limited operating history***

The business of Entheon began in June 2019 and has yet to generate any revenue. Entheon is therefore subject to many of the risks common to early-stage enterprises, including under-capitalization, 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 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 its products 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 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 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 will not increase.

***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 in-house 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.

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. Except for HaluGen's psychedelics pre-screening platform and DNA test kit, Entheon has not yet submitted any psychedelic therapeutic products for approval by regulatory authorities in Canada, the European Union, the United States or elsewhere. For the year ended November 30, 2020, Entheon's subsidiary, Entheon Holdings, incurred a net loss of $4,381,491.

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 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 Products, prepare 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 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 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.

***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.

***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 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 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.

***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.

***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.

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 this AIF.

***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 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.

**Financial and Accounting Risks**

***Liquidity and future financing risk***

Entheon will likely operate at a loss until its business becomes established and it may require additional financing in order to fund future operations and expansion plans. Entheon's ability to secure any required financing to sustain operations and expansion plans will depend in part upon prevailing capital market conditions and business success. There can be no assurance that Entheon will be successful in its efforts to secure any additional financing or additional financing on terms satisfactory to management. Moreover, future activities may require Entheon to alter its capitalization significantly and, if additional financing is raised by issuance of additional Entheon Shares from treasury, control may change and shareholders may suffer dilution. The inability of Entheon to access sufficient capital for its operations could have a material adverse effect on Entheon's financial condition and results of operations.

***Entheon's financial condition would be adversely impacted if its intangible assets become impaired***

Intangibles are evaluated quarterly and are tested for impairment at least annually or when events or changes in circumstances indicate the carrying value of each segment, and collectively Entheon taken as a whole, might exceed its fair value. If Entheon determines that the value of its intangible assets is less than the amounts reflected on its balance sheet, it will be required to reflect an impairment of its intangible assets in the period in which such determination is made. An impairment of its intangible assets would result in its recognizing an expense in the amount of the impairment in the relevant period, which would also result in the reduction of its intangible assets and a corresponding reduction in its stockholders' equity in the relevant period.

***Tax risk***

Entheon is subject to various taxes including, but not limited to the following: income tax; goods and services tax; sales tax; land transfer tax; payroll tax; and equivalent taxes imposed by the taxing authorities in the United States and in Europe. Entheon's tax filings will be subject to audit by various taxation authorities. While Entheon intends to base its tax filings and compliance on the advice of its tax advisors, there can be no assurance that its tax filing positions will never be challenged by a relevant taxation authority resulting in a greater than anticipated tax liability.

**Risks Relating to the Psychedelic Therapy Market and Biotechnology Industry**

***The psychedelic therapy market and industry are relatively new and this industry and market may not continue to exist or grow as anticipated***

Entheon operates its business in a relatively new industry and market. In addition to being subject to general business risks, Entheon must continue to build brand awareness in this industry and market through significant investments in its strategy, its operational capacity, quality assurance and compliance with regulations. In addition, there is no assurance that the industry and market will continue to exist and grow as currently estimated or anticipated or function and evolve in the manner consistent with management's expectations and assumptions. Any event or circumstance that adversely affects the psychedelic therapy industry and market could have a material adverse effect on Entheon's business, financial conditions and results of operations.

***Unfavourable publicity or consumer perception***

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

***The psychedelic therapy industry is difficult to quantify and investors will be reliant on their own estimates of the accuracy of market data***

Because the psychedelic therapy industry is in a nascent stage with uncertain boundaries, there is a lack of information about comparable companies available for potential investors to review in deciding about whether to invest in Entheon and, few, if any, established companies whose business model Entheon can follow or upon whose success Entheon can build. Accordingly, investors will have to rely on their own estimates in deciding about whether to invest in Entheon. There can be no assurance that Entheon's estimates are accurate or that the market size is sufficiently large for its business to grow as projected, which may negatively impact its financial results.

***The psychedelic therapy and biotechnology industries are experiencing rapid growth and increased competition***

The psychedelic therapy industry is undergoing rapid growth and substantial change, which has resulted in an increase in competitors, consolidation and formation of strategic relationships. Acquisitions or other consolidating transactions could harm Entheon in a number of ways, including by losing strategic partners if they are acquired by or enter into relationships with a competitor, losing customers, revenue and market share, or forcing Entheon to expend greater resources to meet new or additional competitive threats, all of which could harm Entheon's operating results.

Additionally, the biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Entheon has competitors in Canada, the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of its competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than it does. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients

and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative transactions in Entheon's target markets with leading companies and research institutions. Entheon's competitors may introduce new products or develop technological advances that compete with Entheon. Entheon cannot predict the timing or impact of competitors introducing new products or technological advances. Such competing products may be safer, more effective, more effectively marketed or sold, or have lower prices or superior performance features than Entheon's products, and this could negatively impact Entheon's business and results of operations. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the psychedelic therapeutic products that Entheon develops obsolete. As a result of all of these factors, its competitors may succeed in obtaining patent protection and/or Health Canada, FDA or EMA approval or discovering, developing and commercializing solutions for the disorders that Entheon is targeting before it does or may develop solutions that are deemed to be more effective or gain greater market acceptance than those of Entheon.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative transactions with large, established companies. In addition, many universities and private and public research institutes may become active in its target disorder areas. Entheon's competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any of the solutions that Entheon is currently developing or that it may develop, which could render its solutions obsolete or non-competitive.

If Entheon's competitors' market solutions that are more effective, safer or less expensive or that reach the market sooner than its future solutions, if any, it may not achieve commercial success. In addition, because of its limited resources, it may be difficult for Entheon to stay abreast of the rapid changes in each technology. If Entheon fails to stay at the forefront of technological change, it may be unable to compete effectively. Technological advances or products developed by its competitors may render its technologies or psychedelic therapeutic products obsolete, less competitive or not economical.

***Forward-Looking Statements May Prove Inaccurate***

Investors are cautioned not to place undue reliance on forward-looking statements. By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties, of both a general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements or contribute to the possibility that predictions, assumptions and uncertainties are found in this AIF under the heading "*Cautionary Statement Regarding Forward-Looking Information*".

## DIVIDENDS AND DISTRIBUTIONS

There are no restrictions that would prevent Entheon from paying dividends on the Entheon Shares, however, Entheon has neither declared nor paid any dividends on the Entheon Shares since incorporation and has not established any dividend or distribution policy. The payment of dividends, if any, in the future, rests within the sole discretion of the Board. The payment of dividends will depend upon Entheon's earnings, its capital requirements and its financial condition, as well as other relevant factors. Entheon intends to retain its earnings to finance growth and expand its operations and does not anticipate paying any dividends on the Entheon Shares in the foreseeable future.

## DESCRIPTION OF CAPITAL STRUCTURE

### Entheon Shares

The authorized share capital of Entheon consists of an unlimited number of Entheon Shares. As of the date hereof there are an aggregate of 54,039,266 Entheon Shares issued and outstanding (on a non-diluted basis) as fully paid and non-assessable common shares in the capital of Entheon.

There are no special rights or restrictions of any nature attached to any of the Entheon Shares. The holders of the Entheon Shares are entitled to receive notice of and to attend and vote at all meetings of the shareholders of Entheon and each Entheon Share confers the right to one vote in person or by proxy at all meetings of the shareholders of Entheon. The holders of the Entheon Shares, subject to the prior rights, if any, of any other class of shares of Entheon are entitled to receive such dividends in any financial year as the Board may by resolution determine. In the event of the liquidation, dissolution or winding-up of Entheon, whether voluntary or involuntary, the holders of the Entheon Shares are entitled to receive, subject to the prior rights, if any, of the holders of any other class of shares of Entheon, the remaining property and assets of Entheon.

### Options

On August 30, 2017, the Board adopted a Stock Option Plan (the "**Option Plan**").

Pursuant to the Option Plan, Entheon may, at its discretion, grant to directors, officers, employees or consultants of Entheon Options to acquire Entheon Shares. It is intended to help Entheon attract, retain and motivate the directors, officers, employees and consultants (collectively the "**Service Providers**") of Entheon and its subsidiaries and to align their personal interests with those of Entheon and its shareholders. In accordance with the Option Plan the total number of securities reserved for issuance will be equivalent to 10% of the number of Entheon Shares issued and outstanding at any given time. The Option Plan is administered by the Board, which has full authority to grant all the options associated with it. Options may be granted under the Option Plan to the Service Providers of Entheon and its subsidiaries, if any, that the Board may designated from time to time. The exercise price will be set by the Board at the time of each stock option grant, but in any event may not be less than the minimum price prescribed by the policies of the CSE. The Option Plan provides that the number of Entheon Shares that may be issued upon the exercise of options granted to any person, as well as all options previously granted by Entheon, may not exceed 10% of the Entheon Shares issued and outstanding, on an undiluted basis, at any given time. In addition, the number of Entheon Shares that may be reserved for issuance to any individual upon the exercise of stock options held by them within a one-year period cannot exceed 5% of the Entheon Shares issued and outstanding, on an undiluted basis, at the grant date without the approval of the disinterested shareholders of Entheon. Subject to early termination in case of dismissal for cause, early retirement, voluntary resignation or dismissal without cause, or in the event of death or disability, all options granted under the Option Plan expire on the date set by the Board as the option expiry date, which must not be later than five years from the option grant date. Options granted under the Option Plan are not transferable or assignable other than by will or pursuant to the laws of succession.

In accordance with CSE Policy 6 – *Distributions*, the terms of an Option may not be amended once issued. If an Option is cancelled prior to its expiry date, Entheon must post notice of the cancellation and shall not grant new Options to the same person until 30 days have elapsed from the date of cancellation. As of the date of this AIF, there are 3,175,000 Options outstanding under the Option Plan.

<u>Cease Trade Orders</u>

At the date of this AIF, no director, executive officer or promoter of the Company is, or was within 10 years prior to the date of this AIF, a director, chief executive officer or chief financial officer of any company that:

(i) was subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant company access to any exemption under Securities Legislation, that was in effect for a period of more than 30 consecutive days, that was issued while the director, executive officer or promoter was acting in the capacity as director, chief executive officer or chief financial officer of the relevant company; or

(ii) was subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant company access to any exemption under Securities Legislation, that was in effect for a period of more than 30 consecutive days, that was issued after the director, executive officer or promoter ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

## MARKET FOR SECURITIES

### Trading Price and Volume

The following table sets out information relating to the monthly trading of the Entheon Shares on the CSE (originally under symbol "MPV" until this changed to "ENBI" upon completion of the Amalgamation) during the year ended November 30, 2020 and up to the date of this AIF:

| **Month** | **High** (Cdn$) | **Low** (Cdn$) | **Volume** (# of Entheon Shares)[1] |
|---|---|---|---|
| November 2019 | $1.18 | $0.60 | 7,373,267 |
| December 2019 | $0.83 | $0.60 | 4,008,939 |
| January 2020 | $0.81 | $0.63 | 4,904,681 |
| February 2020 | $0.95 | $0.55 | 4,580,248 |
| March 2020 | $0.70 | $0.25 | 13,244,852 |
| April 2020 | $0.50 | $0.32 | 8,927,377 |
| May 2020 | $0.50 | $0.39 | 10,210,833 |
| June 2020 | $0.44 | $0.36 | 8,542,024 |
| July 2020 | N/A[2] | N/A[2] | N/A[2] |
| August 2020 | N/A[2] | N/A[2] | N/A[2] |
| September 2020 | N/A[2] | N/A[2] | N/A[2] |
| October 2020 | N/A[2] | N/A[2] | N/A[2] |
| November 2020 | $0.77[2] | $0.465[2] | 7,770,882[2] |
| December 2020 | $1.15 | $0.66 | 14,288,153 |
| January 2021 | $1.35 | $0.78 | 16,535,621 |
| February 2021 | $1.09 | $0.75 | 7,012,828 |
| March 2021 | $0.90 | $0.64 | 3,762,628 |
| April 2021 | $0.72 | $0.42 | 4,972,340 |
| May 2021 | $0.52 | $0.34 | 3,306,870 |
| June 2021[3] | $0.54 | $0.36 | 2,195,105 |

(1) All figures set out in the chart above from November 30, 2019 to October 31, 2020 are given on a pre-Entheon Consolidation basis.

(2) On November 5, 2020 the Company completed the Amalgamation and on November 12, 2020, the Entheon Shares commenced trading on the CSE under the symbol "ENBI". Prior to that time, the Entheon Shares

were halted on July 2, 2020 prior to the announcement and pending completion of the Amalgamation and prior to that the Entheon Shares were trading under symbol "MPV."

(3) June 1 to June 24, 2021.

**Prior Sales**

During the year ended November 30, 2020 and up to the date of this AIF, the Company issued the following securities, which are convertible into Entheon Shares but are not listed or quoted on a marketplace:

| Date of Issuance | Type of Security | Number of Securities | Issue Price Per Security |
|---|---|---|---|
| November 5, 2020 | Options[(1)] | 1,300,000 | N/A |
| November 5, 2020 | Entheon Broker Warrants[(2)] | 211,297 | N/A |
| November 5, 2020 | Financing Warrants[(3)] | 2,108,943 | N/A |
| December 3, 2020 | Options[(1)] | 3,175,000 | N/A |
| December 24, 2020 | Entheon Warrants[(4)] | 2,116,249 | $0.001 |
| December 24, 2020 | Finders' Warrants[(5)] | 168,490 | N/A |
| January 11, 2021 | Entheon Warrants[(6)] | 26,760 | $0.001 |
| March 19, 2021 | Options[(1)] | 50,000 | N/A |

(1) Issued under the Option Plan to certain officers, directors and consultants of the Company.

(2) Issued in exchange for the Subco Broker Warrants outstanding immediately prior to the closing of the Amalgamation.

(3) Issued in exchange for the Subco Warrants outstanding immediately prior to the closing of the Amalgamation.

(4) Issued as part of the December Units in the December 2020 Placement, with each December Unit consisting of one Entheon Share and one-half of one non-transferable Entheon Warrant. See under the heading "*General Development of the Business – Three Year History – Events Subsequent to Fiscal Year End.*"

(5) Issued to certain arm's length finders in connection with the December 2020 Placement. See under the heading "*General Development of the Business – Three Year History – Events Subsequent to Fiscal Year End.*"

(6) Issued as part of the December Units in the second tranche of the December 2020 Placement, with each December Unit consisting of one Entheon Share and one-half of one non-transferable Entheon Warrant. See under the heading "*General Development of the Business – Three Year History – Events Subsequent to Fiscal Year End.*"

## ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER

The following table sets out the Entheon Shares that are, to the Company's knowledge, held in escrow or that are subject to a contractual restriction on transfer and the percentage that number represents of the outstanding securities of that class as at the date of this AIF:

| Designation of class | Number of securities held in escrow or that are subject to a contractual restriction on transfer | Percentage of class[(1)] |
|---|---|---|
| Entheon Shares (Escrow) [(2)] | 2,287,501 | 4.23% |
| Entheon Shares (Contractual Restriction on Transfer) [(3)] | 2,550,000 | 4.72% |

(1) Based on 54,039,266 Entheon Shares issued and outstanding as at the date hereof.

(2) In connection with the Amalgamation and pursuant to the Escrow Agreement these Entheon Shares (the "**Escrowed Securities**") were placed in escrow with Computershare as escrow agent and are subject to a 36-

month release schedule beginning on November 12, 2020 (being the date the Entheon Shares began trading on the CSE), as described below:

| Time | Release Schedule |
|---|---|
| On the Listing Date | 1/10 of the Escrowed Securities |
| 6 months after the Listing Date | 1/6 of the remaining Escrowed Securities |
| 12 months after the Listing Date | 1/5 of the remaining Escrowed Securities |
| 18 months after the Listing Date | 1/4 of the remaining Escrowed Securities |
| 24 months after the Listing Date | 1/3 of the remaining Escrowed Securities |
| 30 months after the Listing Date | 1/2 of the remaining Escrowed Securities |
| 36 months after the Listing Date | the remaining Escrowed Securities |

Assuming there are no changes to the Escrowed Securities initially deposited and no additional Escrowed Securities are deposited, this resulted in a 10% release on the listing date (as defined by NP 46-201), with the remaining Escrowed Securities being released in 15% tranches every 6 months thereafter. The Escrowed Securities are subject to the terms and conditions set out in the Escrow Agreement, which is substantially in the form of 46-201F1 – Escrow Agreement, the form of agreement for escrow arrangements under NP 46-201.

(3) As consideration for all the issued and outstanding HaluGen shares acquired by the Company, the Company issued 5,100,000 Consideration Shares to the shareholders of HaluGen. The Consideration Shares are subject to a 12-month release schedule beginning on January 14, 2021 (being the closing date of the acquisition of HaluGen), as described below:

| Time | Release Schedule |
|---|---|
| January 14, 2021 | 25% of the Consideration Shares |
| May 14, 2021 | 25% of the Consideration Shares |
| September 14, 2021 | 25% of the Consideration Shares |
| January 14, 2022 | 25% of the Consideration Shares. |

## DIRECTORS AND EXECUTIVE OFFICERS

### Name, Occupation and Security Holding

The following table sets forth information with respect to the directors and executive officers of the Company, including their respective provinces or states and countries of residence, their position(s) with the Company, their principal occupations for the last five years, the dates on which they first became directors or officers of the Company and the number of the Entheon Shares beneficially owned, directly or indirectly, or over which control or direction is exercised, by such persons or such persons' respective associates or affiliates.

The directors hold office until the next annual meeting of the Company or until they otherwise cease to hold office in accordance with the Company's By-Laws. The term of office of the executive officers expires at the discretion of the Board.

| Name, Province/State and Country of Residence | Position with the Company | Principal Occupation During the Past Five Years | Period as Director and/or Officer | Number and Percentage of Entheon Shares Held[(2)] |
|---|---|---|---|---|
| Timothy Ko, [(1)(3)] Vancouver, British Columbia, Canada | President, Chief Executive Officer and Director | Founder of Former Entheon and Chief Executive Officer of Former Entheon since incorporation<br>Director of Hyperbridge Technology from 2017 to 2019<br>President of Acom Building Maintenance from 2009 to 2017. | Since November 5, 2020 | 1,300,001 (2.41%) |
| Brandon Schwabe CPA, CGA,<br>Vancouver, British Columbia, Canada | Chief Financial Officer | Chief Financial Officer of Former Entheon since November, 2019<br>Founder of Brandon Schwabe Consulting since May 2019<br>Controller at Union Construction Management October 2017 – April 2019<br>Project Accountant at Kasian Architecture Interior Design & Planning September 2013 – June 2017 | Since November 5, 2020 | 1,250,000 (2.31%) |
| Dr. Andrew Hegle, Vancouver, British Columbia, Canada | Chief Science Officer and Director | Director of Operations of Former Entheon since January, 2020<br>Adjunct professor of Pharmacology at the University of British Columbia since 2015<br>Director of Regulatory Affairs and Quality Assurance for Cannevert Therapeutics Ltd. December 2015 – January 2020 | Since November 5, 2020 | 100,000 (0.19%) |
| Dr. Brian Jahns, Toronto, Ontario, Canada | Chief Business Officer | Chief Business Officer of the Company since February 2021<br>Vice-President Global Marketing at Zyus from January 2020 – February 2021<br>Senior Vice-President, Commercial and Business Development at Trillium Therapeutics Inc. from September 2017 – December 2019<br>Consultant, Oncology and Rare Diseases Biotechnology | Since February 16, 2021 | 36,000 (0.07%) |

| Name, Province/State and Country of Residence | Position with the Company | Principal Occupation During the Past Five Years | Period as Director and/or Officer | Number and Percentage of Entheon Shares Held[(2)] |
|---|---|---|---|---|
| | | Commercialization from July 2016 – September 2017<br><br>Vice President, Sales and Marketing, Oncology (Canada) & Vice-President, Product Strategy (Canada) at Roche from August 2011 – July 2016 | | |
| Dr. Christopher Gondi,[(1)(3)]<br>Dunlap, Illinois, United States | Director | Research Assistant Professor - Departments of Medicine, Surgery and Pathology at the University of Illinois College of Medicine Peoria | Since November 5, 2020 | 500,000 (0.93%) |
| Ruth Chun, [(1)(3)(4)]<br>Campbellville, Ontario, Canada | Director | Chief Executive Officer and Lawyer, Chun Law Professional Corporation since September 2019<br>Senior Legal Counsel, HEXO Corp. May 2019 to June 2019<br>General Counsel and Corporate Secretary, Newstrike Brands Ltd. / Up Cannabis Inc. February 2017 – May 2019<br>Head of Legal & Compliance, Hollard Insurance Group of Companies October 2015 – February 2017<br>Chair, Rössing Pension Fund, March 2016 – August 2017 | Since November 5, 2020 | Nil |

(1) Member of the Audit Committee.
(2) Based on 54,039,266 Entheon Shares issued and outstanding as of the date of this AIF.
(3) Member of the Compensation, Corporate Governance and Nominating Committee.
(4) Chair of the Compensation, Corporate Governance and Nominating Committee.

**Aggregate Ownership of Securities**

As at the date of this AIF, the Company's directors and executive officers as a group beneficially own, directly or indirectly, or exercise control of, 3,186,001 Entheon Shares, collectively representing 5.90% of the 54,039,266 issued and outstanding Entheon Shares.

**Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

Bankruptcies

To the Company's knowledge, no director or executive officer of the Company or any shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company:

(i) is as at the date of this AIF, or has been within the 10 years before the date hereof, a director or executive officer of any company, including the Company, that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or

(ii) has, within the 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or became subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director, executive officer or shareholder.

Penalties or Sanctions

To the Company's knowledge, and other than as disclosed herein, no director or executive officer of the Company or any shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company, has been subject to:

(i) any penalties or sanctions imposed by a court relating to provincial and territorial Securities Legislation or by a provincial and territorial securities regulatory authority or has entered into a settlement agreement with a provincial and territorial securities regulatory authority; or

(ii) any other penalties or sanctions imposed by a court or regulatory body that would be likely to be considered important to a reasonable investor in making an investment decision.

**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 (including other pharmaceutical or biotechnological 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 best of 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.

## PROMOTERS

Timothy Ko, the President, Chief Executive Officer and a director of Entheon is also a promoter of Entheon. Mr. Ko has ownership and control of 1,300,001 Entheon Shares, and 575,000 Options representing 2.41% of the issued and outstanding Entheon Shares and 18.11% of the issued and outstanding Options, respectively in each

case as of the date of this AIF. Mr. Ko does not beneficially own, directly or indirectly, or exercise control over, any voting or equity securities in any subsidiaries of Entheon. No asset was acquired within the two years before the date of the AIF or thereafter, or is to be acquired, by Entheon or by a subsidiary of Entheon from Mr. Ko. For further information regarding Mr. Ko please see information under the heading "*Directors and Executive Officers*."

## LEGAL PROCEEDINGS AND REGULATORY ACTIONS

The Company is not, and was not during the most recently completed financial year, or from the end of the most recently completed financial year to the date of this AIF, a party to, nor was any of its property the subject of, any legal proceedings or regulatory actions material to the Company, and no such proceedings or actions are known to be contemplated.

## INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

No director, executive officer, or principal shareholder of Entheon or an associate or affiliate of a director, executive officer or principal shareholder of Entheon has or had any material interest, direct or indirect, in any transaction within the three years before the date of this AIF, or in any proposed transaction, that has materially affected or will materially affect Entheon.

## TRANSFER AGENTS AND REGISTRARS

The transfer agent and registrar of Entheon is Computershare Trust Company of Canada of 510 Burrard Street, 3rd Floor, Vancouver, British Columbia, Canada V6C 3B9.

## MATERIAL CONTRACTS

The following is a summary of each material contract, other than contracts entered into in the ordinary course of Entheon's business, that was entered into in the financial year ending November 30, 2020, or up to the date of this AIF, that is still in effect:

1) The Amalgamation Agreement. See "*General Development of the Business – Three Year History*" for further details.

2) The CHDR Clinical Study Agreement. See "*General Development of the Business – Three Year History*" and "*Description of the Business – Summary – Economic Dependence*" for further details.

3) The Psygen Supply Agreement. See "*General Development of the Business – Three Year History*" and "*Description of the Business – Summary – Economic Dependence*" for further details.

4) The Lobo Agreement. See "*General Development of the Business – Three Year History – Events Subsequent to Fiscal Year Ended November 30, 2020"* for further details.

5) The Ofichem Services Agreement. See "*General Development of the Business – Three Year History*" and "*Description of the Business – Summary – Economic Dependence*" for further details.

## INTERESTS OF EXPERTS

No person or company whose profession or business gives authority to a report, valuation, statement or opinion made by the person or company are named in this AIF as having prepared or certified any of the aforementioned documents or any part thereof described in this AIF.

Manning Elliott LLP, as auditor of the Company, has confirmed that they are independent with respect to the Company within the meaning of the Code of Professional Conduct of the Chartered Professional Accountants of British Columbia.

## AUDIT COMMITTEE

### Audit Committee Charter

The Audit Committee Charter sets out the Audit Committee's responsibilities and authority, procedures governing meetings, qualifications for membership and particulars governing the role of the Chair. A copy of the Audit Committee Charter is attached as Appendix "A" hereto.

### Composition of the Audit Committee

As at the date of this AIF, the following individuals are the current members of the Audit Committee and will hold office until the next annual general meeting of shareholders of the Company:

| | | |
|---|---|---|
| Dr. Christopher Gondi (Chair) | Independent(1) | Financially Literate(1) |
| Timothy Ko | Not Independent(2) | Financially Literate(1) |
| Ruth Chun | Independent(1) | Financially Literate(1) |

(1) As defined by National Instrument 52-110 – *Audit Committees* ("**NI 52-110**").

(2) Mr. Ko is the current President and CEO of the Company and would not be considered independent under NI 52-110.

The members of the Audit Committee are appointed by the Board at its first meeting following the annual Shareholders' meeting. Unless a chair is elected by the full Board, the members of the Audit Committee designate a chair by a majority vote of the full Audit Committee membership.

### Relevant Education and Experience

The relevant education and/or experience of each member of the Audit Committee is as follows:

*Timothy Ko*

Timothy Ko has a broad background of leading private ventures in the service sector, investor relations, retail and technology. Most recently from 2017 to 2019 he served as Director of Hyperbridge Technology, a company focused on the development of decentralized technologies that facilitate crowdfunding. Previous to that Mr. Ko served as President of Acom Building Maintenance.

*Ruth Chun*

Ms. Chun has an Honours Bachelor of Arts from University of Toronto (Trinity College), Master of Arts (University of Toronto) and Juris Doctor (Queen's University), and is a lawyer admitted to practice in Ontario, New York and Namibia. Ms. Chun advises numerous plant-based medicine companies in the cannabis and psychedelics sectors as well as technology, clean energy, branding and consumer packaged goods companies. From February 2017 to May 2019, she was general counsel and corporate secretary for Newstrike Brands Ltd. / Up Cannabis Inc., a cannabis producer, and was active in its listing on the TSX Venture Exchange, raising over $150 million in financing and its sale to HEXO Corp., a large cannabis company, where she was senior legal counsel following the company merger from May 2019 until the end of June 2019. Previously, Ms. Chun was the head of legal and

compliance for the Hollard Insurance group of companies and was the first female member of its executive committee from October 2015 to February 2017. She was also a partner at ENS Africa, Africa's largest law firm, where she specialized in natural resources and financial services law from April 2011 to September 2015 and was previously an associate at the firm and was previously at McCarthy Tetrault and Shearman & Sterling law firms. She also chaired the Rössing Pension Fund, Rio Tinto's defined benefits fund from March 2016 to August 2017.

*Dr. Christopher Gondi*

Dr. Christopher Gondi has served on the Company's Audit Committee, where he has deepened his understanding of accounting principles and has gained experience preparing, auditing, analyzing and evaluating the Company's financial statements.

**Audit Committee Oversight**

At no time since the commencement of the Company's most recently completed financial year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board.

**Pre-Approval Policies and Procedures**

The audit committee of the Corporation has adopted specific policies and procedures for the engagement of non-audit services as described in the audit committee's charter attached hereto as Schedule "A".

**External Auditor Service Fees (By Category)**

The following table sets out the aggregate fees billed by the Company's former external auditors, Raymond Chabot Grant Thornton LLP, and to Manning Elliott LLP, the Company's current external auditors, for the years ended March 31, 2020, and 2019 and for the transition year ended November 30, 2020.

| *Financial Year Ending* | *Audit Fees*[1] | *Audit Related Fees*[2] | *Tax Fees*[3] | *All Other Fees*[4] |
|---|---|---|---|---|
| March 31, 2019[7] | $22,500 | - | - | - |
| March 31, 2020[7] | $10,000 | - | - | $1,225[5] |
| November 30, 2020[7] | - | $17,989 | - | - |
| November 30, 2020[8] | $37,500 | $16,000[6] | $23,500 | - |

(1) "Audit Fees" include the aggregate fees billed in each financial year for audit fees.
(2) "Audit Related Fees" include the aggregate fees billed in each financial year for assurance and related services to the performance of the audit or review of the Company's financial statements not already disclosed under "Audit Fees".
(3) "Tax Fees" are the aggregate fees billed by the auditor for tax compliance, tax advice and tax planning.
(4) "All Other Fees" include aggregate fees billed for products or services not already reported in the above table.
(5) Fees charged for prospectus reading services.
(6) Fees relating to accounting and finance advisory services related to the Amalgamation.
(7) Billed by Raymond Chabot Grant Thornton LLP.
(8) Billed by Manning Elliott LLP during the period beginning December 1, 2019 and ending November 30, 2020.

**Reliance on Certain Exemptions**

The Company is relying on the exemption in section 6.1 of NI 52-110 from the requirements of Parts 3 (Composition of the Audit Committee) and 5 (Reporting Obligations).

## ADDITIONAL INFORMATION

Additional information relating to the Company may be found under the Company's profile on SEDAR at www.sedar.com.

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans is contained in the Company's information circular for its most recent annual and special meeting of shareholders filed on SEDAR on August 19, 2020, as well as the Company's CSE Form 2A Listing Statement filed on SEDAR on November 11, 2020 prepared in connection with the listing of the Entheon Shares on the CSE.

Additional financial information is provided in the Company's audited annual financial statements and accompanying management's discussion and analysis ("**MD&A**") for the year ended November 30, 2020.

## APPENDIX “A”

## AUDIT COMMITTEE CHARTER

### 1. Mandate and Purpose of the Committee

The Audit Committee (the "**Committee**") of the board of directors (the "**Board**") of Entheon Biomedical Corp. (the "**Corporation**") is a standing committee of the Board whose primary function is to assist the Board in fulfilling its oversight responsibilities relating to:

(a) the integrity of the Corporation’s financial statements;

(b) the Corporation’s compliance with legal and regulatory requirements, as they relate to the Corporation’s financial statements;

(c) the qualifications, independence and performance of the Corporation’s auditor;

(d) internal controls and disclosure controls;

(e) the performance of the Corporation’s internal audit function;

(f) consideration and approval of certain related party transactions; and

(g) performing the additional duties set out in this Charter or otherwise delegated to the Committee by the Board.

### 2. Authority

The Committee has the authority to:

(a) engage and compensate independent counsel and other advisors as it determines necessary or advisable to carry out its duties; and

(b) communicate directly with the Corporation’s auditor.

The Committee has the authority to delegate to individual members or subcommittees of the Committee.

### 3. Composition and Expertise

The Committee shall be composed of a minimum of three members, each of whom is a director of the Corporation. The majority of the Committee's members must not be officers or employees of the Corporation or an affiliate of the Corporation.

Committee members shall be appointed annually by the Board at the first meeting of the Board following each annual meeting of shareholders. Committee members hold office until the next annual meeting of shareholders or until they are removed by the Board or cease to be directors of the Corporation.

The Board shall appoint one member of the Committee to act as Chairman of the Committee. If the Chairman of the Committee is absent from any meeting, the Committee shall select one of the other members of the Committee to preside at that meeting.

### 4. Meetings

Any member of the Committee or the auditor may call a meeting of the Committee. The Committee shall meet at least four times per year and as many additional times as the Committee deems necessary to carry out its duties. The Chairman shall develop and set the Committee’s agenda, in consultation with other members of the Committee, the Board and senior management.

Notice of the time and place of every meeting shall be given in writing to each member of the Committee, at least 72 hours (excluding holidays) prior to the time fixed for such meeting. The Corporation’s auditor shall be

given notice of every meeting of the Committee and, at the expense of the Corporation, shall be entitled to attend and be heard thereat. If requested by a member of the Committee, the Corporation's auditor shall attend every meeting of the Committee held during the term of office of the Corporation's auditor.

A majority of the Committee who are not officers or employees of the Corporation or an affiliate of the Corporation shall constitute a quorum. No business may be transacted by the Committee except at a meeting of its members at which a quorum of the Committee is present in person or by means of such telephonic, electronic or other communications facilities as permit all persons participating in the meeting to communicate with each other simultaneously and instantaneously. Business may also be transacted by the unanimous written consent resolutions of the members of the Committee, which when so approved shall be deemed to be resolutions passed at a duly called and constituted meeting of the Committee.

The Committee may invite such directors, officers and employees of the Corporation and advisors as it sees fit from time to time to attend meetings of the Committee.

The Committee shall meet without management present whenever the Committee deems it appropriate.

The Committee shall appoint a Secretary who need not be a director or officer of the Corporation. Minutes of the meetings of the Committee shall be recorded and maintained by the Secretary and shall be subsequently presented to the Committee for review and approval.

**5. Committee and Charter Review**

The Committee shall conduct an annual review and assessment of its performance, effectiveness and contribution, including a review of its compliance with this Charter. The Committee shall conduct such review and assessment in such manner as it deems appropriate and report the results thereof to the Board.

The Committee shall also review and assess the adequacy of this Charter on an annual basis, taking into account all legislative and regulatory requirements applicable to the Committee, as well as any guidelines recommended by regulators or the Canadian Securities Exchange and shall recommend changes to the Board thereon.

**6. Reporting to the Board**

The Committee shall report to the Board in a timely manner with respect to each of its meetings held. This report may take the form of circulating copies of the minutes of each meeting held.

**7. Duties and Responsibilities**

(a) **Financial Reporting**

The Committee is responsible for reviewing and recommending approval to the Board of the Corporation's annual and interim financial statements, any auditor's report thereon, MD&A and related news releases, before they are published.

The Committee is also responsible for:

(i) being satisfied that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements, other than the public disclosure referred to in the preceding paragraph, and for periodically assessing the adequacy of those procedures;

(ii) engaging the Corporation's auditor to perform a review of the interim financial statements and receiving from the Corporation's auditor a formal report on the auditor's review of such interim financial statements;

(iii) discussing with management and the Corporation's auditor the quality of applicable accounting principles and financial reporting standards, not just the acceptability of thereof;

(iv) discussing with management any significant variances between comparative reporting periods; and

(v) in the course of discussion with management and the Corporation's auditor, identifying problems or areas of concern and ensuring such matters are satisfactorily resolved.

(b) **Auditor**

The Committee is responsible for recommending to the Board:

(i) the auditor to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Corporation; and

(ii) the compensation of the Corporation's auditor.

The Corporation's auditor reports directly to the Committee. The Committee is directly responsible for overseeing the work of the Corporation's auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Corporation, including the resolution of disagreements between management and the Corporation's auditor regarding financial reporting.

(c) **Relationship with the Auditor**

The Committee is responsible for reviewing the proposed audit plan and proposed audit fees. The Committee is also responsible for:

(i) establishing effective communication processes with management and the Corporation's auditor so that it can objectively monitor the quality and effectiveness of the auditor's relationship with management and the Committee;

(ii) receiving and reviewing regular feedback from the auditor on the progress against the approved audit plan, important findings, recommendations for improvements and the auditor's final report;

(iii) reviewing, at least annually, a report from the auditor on all relationships and engagements for non-audit services that may be reasonably thought to bear on the independence of the auditor; and

(iv) meeting in camera with the auditor whenever the Committee deems it appropriate.

(d) **Accounting Policies**

The Committee is responsible for:

(i) reviewing the Corporation's accounting policy note to ensure completeness and acceptability with applicable accounting principles and financial reporting standards as part of the approval of the financial statements;

(ii) discussing and reviewing the impact of proposed changes in accounting standards or securities policies or regulations;

(iii) reviewing with management and the auditor any proposed changes in major accounting policies and key estimates and judgments that may be material to financial reporting;

(iv) discussing with management and the auditor the acceptability, degree of aggressiveness/conservatism and quality of underlying accounting policies and key estimates and judgments; and

(v) discussing with management and the auditor the clarity and completeness of the Corporation's financial disclosures.

(e) **Risk and Uncertainty**

The Committee is responsible for reviewing, as part of its approval of the financial statements:

(i) uncertainty notes and disclosures; and

(ii) MD&A disclosures.

The Committee, in consultation with management, will identify the principal business risks and decide on the Corporation's "appetite" for risk. The Committee is responsible for reviewing related risk management policies and recommending such policies for approval by the Board. The Committee is then responsible for communicating and assigning to the applicable Board committee such policies for implementation and ongoing monitoring.

The Committee is responsible for requesting the auditor's opinion of management's assessment of significant risks facing the Corporation and how effectively they are managed or controlled.

(f) **Controls and Control Deviations**

The Committee is responsible for reviewing:

(i) the plan and scope of the annual audit with respect to planned reliance and testing of controls; and

(ii) major points contained in the auditor's management letter resulting from control evaluation and testing.

The Committee is also responsible for receiving reports from management when significant control deviations occur.

(g) **Compliance with Laws and Regulations**

The Committee is responsible for reviewing regular reports from management and others (e.g. auditors) concerning the Corporation's compliance with financial related laws and regulations, such as:

(i) tax and financial reporting laws and regulations;

(ii) legal withholdings requirements;

(iii) environmental protection laws; and

(iv) other matters for which directors face liability exposure.

(h) **Related Party Transactions**

All transactions between the Corporation and a related party (each a "**related party transaction**"), other than transactions entered into in the ordinary course of business, shall be presented to the Committee for consideration.

The term "related party" includes (i) all directors, officers, employees, consultants and their associates (as that term is defined in the Securities Act (British Columbia), as well as all entities with common directors, officers, employees and consultants (each "**general related parties**"), and (ii) all other individuals and entities having beneficial ownership of, or control or direction over, directly or indirectly securities of the Corporation carrying more than 10% of the voting rights attached to all of the Corporation's outstanding voting securities (each "**10% shareholders**").

Related party transactions involving general related parties which are not material to the Corporation require review and approval by the Committee. Related party transactions that are material to the Corporation or that involve 10% shareholders require approval by the Board,

following review thereof by the Committee and the Committee providing its recommendation thereon to the Board.

**8. Non-Audit Services**

All non-audit services to be provided to the Corporation or its subsidiary entities by the Corporation's auditor must be pre-approved by the Committee.

**9. Submission Systems and Treatment of Complaints**

The Committee is responsible for establishing procedures for:

(a) the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls, or auditing matters; and

(b) the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters.

The Committee is responsible for reviewing complaints and concerns that are brought to the attention of the Chairman of the Audit Committee and for ensuring that any such complaints and concerns are appropriately addressed. The Committee shall report quarterly to the Board on the status of any complaints or concerns received by the Committee.

**10. Procedure For Reporting Of Fraud Or Control Weaknesses**

Each employee is expected to report situations in which he or she suspects fraud or is aware of any internal control weaknesses. An employee should treat suspected fraud seriously, and ensure that the situation is brought to the attention of the Committee. In addition, weaknesses in the internal control procedures of the Corporation that may result in errors or omissions in financial information, or that create a risk of potential fraud or loss of the Corporation's assets, should be brought to the attention of both management and the Committee.

To facilitate the reporting of suspected fraud, it is the policy of Corporation that the employee (the "whistleblower") has anonymous and direct access to the Chairman of the Audit Committee. Should a new Chairman be appointed prior to the updating of this document, the current Chairman will ensure that the whistleblower is able to reach the new Chairman in a timely manner. In the event that the Chairman of the Audit Committee cannot be reached, the whistleblower should contact the Chairman of the Board.

In addition, it is the policy of the Corporation that employees concerned about reporting internal control weaknesses directly to management are able to report such weaknesses to the Committee anonymously. In this case, the employee should follow the same procedure detailed above for reporting suspected fraud.

**11. Hiring Policies**

The Committee is responsible for reviewing and approving the Corporation's hiring policies regarding partners, employees and former partners and employees of the present and former auditor of the Corporation.