



**ENTHEON BIOMEDICAL CORP.**

**595 Howe Street, 10<sup>th</sup> floor, Vancouver,  
British Columbia, V6C 2T5**

---

**FORM 2A**

**LISTING STATEMENT**

---

**Dated as at November 12, 2020**

**Dimethyltryptamine (“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.**

|            |                                                                        |           |
|------------|------------------------------------------------------------------------|-----------|
| <b>1.</b>  | <b>TABLE OF CONTENTS</b>                                               |           |
| <b>2.</b>  | <b>Corporate Structure .....</b>                                       | <b>9</b>  |
| <b>3.</b>  | <b>General Development of the Business.....</b>                        | <b>10</b> |
| <b>4.</b>  | <b>Narrative Description of the Business.....</b>                      | <b>19</b> |
| <b>5.</b>  | <b>Selected Consolidated Financial Information .....</b>               | <b>42</b> |
| <b>6.</b>  | <b>Management’s Discussion and Analysis .....</b>                      | <b>43</b> |
| <b>7.</b>  | <b>Market for Securities .....</b>                                     | <b>43</b> |
| <b>8.</b>  | <b>Consolidated Capitalization .....</b>                               | <b>44</b> |
| <b>9.</b>  | <b>Options to Purchase Securities .....</b>                            | <b>45</b> |
| <b>10.</b> | <b>Description of Securities.....</b>                                  | <b>45</b> |
| <b>11.</b> | <b>Escrowed Securities .....</b>                                       | <b>46</b> |
| <b>12.</b> | <b>Principal Shareholders .....</b>                                    | <b>47</b> |
| <b>13.</b> | <b>Directors and Officers.....</b>                                     | <b>47</b> |
| <b>14.</b> | <b>Capitalization .....</b>                                            | <b>54</b> |
| <b>15.</b> | <b>Executive Compensation .....</b>                                    | <b>56</b> |
| <b>16.</b> | <b>Indebtedness of Directors and Executive Officers.....</b>           | <b>59</b> |
| <b>17.</b> | <b>Risk Factors .....</b>                                              | <b>60</b> |
| <b>18.</b> | <b>Promoters .....</b>                                                 | <b>76</b> |
| <b>19.</b> | <b>Legal Proceedings.....</b>                                          | <b>76</b> |
| <b>20.</b> | <b>Interest of Management and Others in Material Transactions.....</b> | <b>76</b> |
| <b>21.</b> | <b>Auditors, Transfer Agents and Registrars.....</b>                   | <b>77</b> |
| <b>22.</b> | <b>Material Contracts .....</b>                                        | <b>77</b> |
| <b>23.</b> | <b>Interest of Experts.....</b>                                        | <b>77</b> |
| <b>24.</b> | <b>Other Material Facts .....</b>                                      | <b>77</b> |
| <b>25.</b> | <b>Financial Statements.....</b>                                       | <b>77</b> |
|            | <b>SCHEDULE “A” .....</b>                                              | <b>79</b> |

|                                                     |           |
|-----------------------------------------------------|-----------|
| <b>SCHEDULE "B" .....</b>                           | <b>80</b> |
| <b>SCHEDULE "C" .....</b>                           | <b>81</b> |
| <b>SCHEDULE "D" .....</b>                           | <b>82</b> |
| <b>SCHEDULE "E" .....</b>                           | <b>83</b> |
| <b>SCHEDULE "F" .....</b>                           | <b>84</b> |
| <b>SCHEDULE "G" .....</b>                           | <b>85</b> |
| <b>CERTIFICATE OF ENTHEON BIOMEDICAL CORP. ....</b> | <b>86</b> |
| <b>CERTIFICATE OF ENTHEON BIOMEDICAL CORP. ....</b> | <b>87</b> |

Schedule "A" - Financial Statements of Entheon for the fiscal years ended March 31, 2020 (audited) and March 31, 2019 (audited)

Schedule "B" - MD&A of Entheon for the fiscal years ended March 31, 2020 and March 31, 2019

Schedule "C" - Financial Statements of Entheon for the three month period ended June 30, 2020 (unaudited) and June 30, 2019 (unaudited)

Schedule "D" - MD&A of Entheon for the three month period ended June 30, 2020 and June 30, 2019

Schedule "E" - Financial Statements of Former Entheon for the fiscal year ended November 30, 2019 (audited) and the nine-month period ended August 31, 2020 (unaudited)

Schedule "F" - MD&A of Former Entheon for the fiscal year ended November 30, 2019 and the nine-month period ended August 31, 2020

Schedule "G" - Pro Forma Financial Statements of Entheon

## Glossary of Terms

The following terms used in this Listing Statement have the following meanings. This is not an exhaustive list of defined terms used in this Listing Statement and additional terms are defined throughout the Listing Statement.

**"5-MeO-DMT"** has the meaning ascribed thereto under the heading *"Narrative Description of the Business – Overview"*.

**"Amalgamation Agreement"** means the amalgamation agreement entered into on June 30, 2020, by and between Former Entheon, MPV Exploration Inc. and Subco, and any supplementary or ancillary agreement, instrument or document thereto, all as may be amended from time to time.

**"Amalgamation"** means the amalgamation of Former Entheon and Subco in accordance with the provisions of the BCBCA and the terms and conditions of the Amalgamation Agreement.

**"API"** means active product ingredient.

**"BCBCA"** means the *Business Corporations Act* (British Columbia) S.B.C. 2002 c.57, as amended, including the regulations promulgated thereunder.

**"BCSC"** means the British Columbia Securities Commission.

**"Broker Warrant Unit"** means one Subco Class A Share and one-half of one Underlying Broker Warrant.

**"Broker Warrants"** means the broker warrants exercisable into 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.

**"CBCA"** means the Canada *Business Corporations Act* (R.S.C., 1985, c. C-44).

**"CDSA"** means the Canada *Controlled Drug and Substances Act* (S.C. 1996, c. 19).

**"CHDR Clinical Study Agreement"** means the clinical trial agreement dated October 7, 2020 between Entheon and the CHDR.

**"CHDR"** means the Centre for Human Drug Research located in Leiden, Netherlands.

**"Common Shares"** means the post-Consolidation common shares in the capital of Entheon.

**"company"** unless specifically indicated otherwise, means a corporation, incorporated association or organization, body corporate, partnership, trust, association or other entity other than an individual.

**"Consolidation"** means the consolidation of the Common Shares on the basis one post-Consolidation common share for every three pre-Consolidation common shares held by a shareholder of Entheon prior to completion of the Transaction.

**"CRO"** means a contract research organization.

**"CSA"** means the United States *Controlled Substances Act of 1970*.

**"CSE Policy 2"** means the CSE Policy 2 – *Qualification for Listing*.

**"CSE"** means the Canadian Securities Exchange.

**“DMT Delivery System”** has the meaning ascribed thereto under the heading *“General Development of the Business – History – Overview of the Business”*.

**“DMT Products”** has the meaning ascribed thereto under the heading *“General Development of the Business – History – Overview of the Business”*.

**“DMT Solutions”** means the DMT Delivery System and the DMT Products.

**“DMT”** means Dimethyltryptamine, a chemical substance that occurs in many plants and animals and which is both a derivative and a structural analog of tryptamine.

**“Dosing Strategies”** has the meaning ascribed thereto under the heading *“General Development of the Business – History – Overview of the Business”*.

**“Drug Master File”** has the meaning ascribed thereto under the heading *“General Development of the Business – History – Summary of the Regulatory Approval Process”*.

**“EMA”** means the European Medicines Agency.

**“Entheon Board”** means the board of directors of Entheon.

**“Entheon Holdings”** means Entheon Holdings Corp., the corporation formed as a result of the amalgamation of Subco and Former Entheon in connection with the Transaction.

**“Entheon Warrants”** means the common share purchase warrants of Former Entheon that were outstanding prior to completion of the Transaction, with exercise prices ranging from \$0.50 to \$0.60 and having expiry dates ranging from December 18, 2021 to June 3, 2022.

**“Entheon”** means Entheon Biomedical Corp. (formerly, MPV Exploration Inc. prior to completion of the Transaction), a corporation incorporated under the laws of Canada.

**“Escrow Agent”** means Computershare Trust Company of Canada.

**“Escrow Agreement”** means the escrow agreement dated November 5, 2020, substantially in Form 46-201F1, entered into among the Escrowed Entheon Shareholders and the Escrow Agent, in relation to the Common Shares issued to the Escrowed Entheon Shareholders being held in escrow.

**“Escrowed Entheon Shareholders”** means each of Timothy Ko, Brandon Schwabe and Christopher Gondi, all of whom are subject to escrow restrictions pursuant to the Escrow Agreement.

**“Escrowed Securities”** means the Common Shares held by the Escrowed Entheon Shareholders, subject to the Escrow Agreement.

**“Exchange Ratio”** means one Common Share issued for each one Former Entheon Share, which Former Entheon Shareholders received in connection with the Amalgamation.

**“FDA”** means the United States Food and Drug Administration.

**“Finders’ Unit”** means one Subco Class A Share and one-half of one Subco Financing Warrant, issued to certain finders in connection with the Subco Private Placement.

**“Former Entheon Shareholders”** means the holders of the Former Entheon Shares, prior to completion of the Transaction.

**"Former Entheon Shares"** means the Class A voting common shares in the capital of Former Entheon that were issued and outstanding prior to completion of the Transaction.

**"Former Entheon"** means Entheon Biomedical Corp. as it existed prior to completion of the Transaction, a private corporation existing under the laws of the Province of British Columbia.

**"GMP"** means Good Manufacturing Practice regulations recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.

**"Governmental Authority"** means any domestic or foreign government whether federal, provincial, state or municipal and any branch or department thereof or any governmental agency, governmental department, governmental tribunal or governmental commission of any kind whatsoever.

**"Health Canada"** means the Health Products and Food Branch of Health Canada.

**"Insider"** if used in relation to an issuer, means:

- (a) a director or officer of such issuer;
- (b) a director or officer of a Person that is an Insider or subsidiary of such issuer;
- (c) a Person that beneficially owns or controls, directly or indirectly, voting shares carrying more than 10% of the voting rights attached to all outstanding voting shares of such issuer; or
- (d) such issuer itself if it holds any of its own securities.

**"IMPD"** or **"Investigational Medicinal Product Dossier"** has the meaning ascribed thereto under the heading *"General Development of the Business – History – Summary of the Regulatory Approval Process"*.

**"Investigator Brochure"** has the meaning ascribed thereto under the heading *"General Development of the Business – History – Summary of the Regulatory Approval Process"*.

**"Listing Statement"** means this listing statement.

**"Management Agreements"** means management employment contracts entered into between Entheon and each of Timothy Ko, Andrew Hegle and Brandon Schwabe.

**"MD&A"** means management's discussion and analysis as such term is defined in National Instrument 51-102 – *Continuous Disclosure Obligations*.

**"MPV Financing Warrant"** means a Common Share purchase warrant entitling the holder to purchase a Common Share at a price of \$0.60 for a period of two years from the date the Subco Subscription Receipts were converted into Subco Units.

**"MPV Warrants"** means the warrants to acquire pre-Consolidation common shares of Entheon that were outstanding immediately prior to completion of the Transaction.

**"NP 46-201"** means National Policy 46-201 – *Escrow for Initial Public Offerings*.

**"Options"** means the stock options of Entheon exercisable to purchase Common Shares.

**"Party"** means a party to the Amalgamation Agreement, being Former Entheon, MPV Exploration Inc. and Subco, and **"Parties"** means any one of them.

**"Person"** includes any natural person, partnership, limited partnership, joint venture, syndicate, sole proprietorship, body corporate with or without share capital, unincorporated association, trust, trustee, executor, administrator or other legal personal representative.

**"Phase 2 Nicotine Study"** has the meaning ascribed thereto under the heading *"Narrative Description of the Business – Research and Development Studies – Additional Steps Required for Development & Commercialization"*.

**"Phase 1 Study"** has the meaning ascribed thereto under the heading *"General Development of the Business – History - Contracts"*.

**"Preclinical Studies"** has the meaning ascribed thereto under the heading *"Narrative Description of the Business – Research and Development Studies – Timing, Costs, Stage of Development & Major Components of Proposed Studies"*.

**"Psygen Supply Agreement"** means the definitive supply agreement dated August 21, 2020, as amended on October 9, 2020, by and between Entheon Holdings and Psygen.

**"Psygen"** means Psygen Labs Inc.

**"Registrar"** means the Registrar of Corporations or a Deputy Registrar of Corporations for the Province of British Columbia duly appointed under the BCBCA.

**"Replacement Broker Warrant Unit"** means a unit of Entheon comprised of one Common Share and one-half of one Underlying Replacement Broker Warrant;

**"Replacement Broker Warrants"** means the broker warrants of Entheon exercisable to purchase Replacement Broker Warrant Units at an exercise price of \$0.375 for a period of two years from the closing of the Subco Private Placement;

**"Stock Option Plan"** means the stock option plan of Entheon.

**"Subco Broker Exchange Ratio"** means one Replacement Broker Warrant issued for each one Broker Warrant, which holders of Broker Warrants received in connection with the Amalgamation;

**"Subco Class A Shares"** means Class A non-voting shares in the capital of Subco.

**"Subco Financing Warrant"** means 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 Subco Subscription Receipts were converted into Subco Units.

**"Subco Private Placement"** means the non-brokered private placement of Subco that closed on September 3, 2020, whereby Subco sold an aggregate of 4,117,886 Subco Subscription Receipts at a price of \$0.375 per Subco Subscription Receipt for gross proceeds of \$1,544,207, undertaken in connection with the Transaction.

**"Subco Subscription Receipt"** means a subscription receipt of Subco issued in connection with the Subco Private Placement, each of which were automatically converted into a Subco Unit on completion of the Amalgamation.

**"Subco Unit"** means one Subco Class A Share and one-half of one Subco Financing Warrant.

**"Subco"** means 1254912 B.C. Ltd., a corporation incorporated under the laws of the Province of British Columbia.

**"Transaction"** means the arm's length acquisition by Entheon of all of the issued and outstanding securities of former Entheon by way of a three-cornered amalgamation, and the related transactions and corporate proceedings contemplated in the Amalgamation Agreement.

**“UN71”** means the United Nations Convention on Psychotropic Substances, 1971 used by European Union member states in governing the classification and legitimate use of drugs and precursors.

**“Underlying Broker Warrant”** means 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 Subco Subscription Receipts were converted into Subco Units.

**“Underlying Replacement Broker Warrant”** means a Common Share purchase warrant entitling the holder to purchase a Common Share at a price of \$0.60 for a period of two years from the date the Subco Subscription Receipts were converted into Subco Units.

**“Warrants”** means the Common Share purchase warrants of Entheon, exercisable to purchase Common Shares (and for greater certainty includes the Entheon Warrants, the MPV Warrants and the MPV Financing Warrants).

**“Working Capital”** means current assets less current liabilities.

### Currency

In this Listing Statement, unless otherwise indicated, all dollar amounts are expressed in Canadian dollars and references to “\$” are to Canadian dollars. All United States dollars expressed in Canadian dollars are based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257. All Euros expressed in Canadian dollars are based on the Bank of Canada exchange rate on November 2, 2020 of 1.5421.

### Forward Looking Statements

The information provided in this Listing Statement, including information incorporated by reference, may contain “forward-looking statements” or “forward-looking information” (collectively referred to hereafter as “forward-looking statements”) within the meaning of applicable Canadian securities legislation.

All statements, other than statements of historical facts, included in this Listing Statement that address activities, events or developments that Entheon expect or anticipate will, or may, occur in the future, including statements about efficacy of products or treatment; the completion of clinical trials; expected change in regulations; Entheon being able to generate cash flow from operations and obtain necessary financing on acceptable terms; general economic, financial market, regulatory and political conditions in which Entheon operates will remain the same; Entheon being able to compete in the psychedelic therapeutics industry; Entheon being able to manage anticipated and unanticipated costs; Entheon being able to maintain internal controls over financial reporting and disclosure, and procedures; Entheon being able to maintain consumer interest in Entheon’s products and services; the timely receipt of any required regulatory approvals; Entheon’s ability to obtain qualified staff, equipment and services in a timely and cost efficient manner; Entheon’s ability to conduct operations in a safe, efficient and effective manner; Entheon expected use of available funds; the expected benefits of the Transaction and Entheon’s proposed business objectives, milestones, plans and strategies, Entheon’s business prospects and future trends. In some cases, forward-looking statements are preceded by, followed by or include words such as “may”, “will”, “would”, “could”, “should”, “believes”, “estimates”, “projects”, “potential”, “expects”, “plans”, “intends”, “anticipates”, “targeted”, “continues”, “forecasts”, “designed”, “goal”, or the negative of those words or other similar or comparable words.

Forward-looking statements are not a guarantee of future performance and are based upon a number of, including, without limitation, assumptions about:

- the anticipated effects and benefits of the Transaction;
- the support and continued support of shareholders of Entheon;
- changes in regulations and legislation regarding psychedelic therapy;
- Entheon’s ability to obtain FDA, EMA or Health Canada approval, within the time frame required or at all;

- changes in the psychedelic therapy market;
- unanticipated clinical study results or effects;
- management's expectation as to market growth and market trends;
- Entheon's ability to retain and maintain the technical and scientific staff required to develop its psychedelic protocols;
- changes in consumer perception of psychedelic-based products;
- future economic conditions;
- the general economic, financial market, regulatory and political conditions in which Entheon operates;
- competition;
- anticipated and unanticipated costs;
- the ability of Entheon to generate cash flow from operations and obtain any necessary financing on acceptable terms; and
- the ability of Entheon to obtain qualified staff and services in a timely and cost-efficient manner.

Although management of Entheon believes that the assumptions made and the expectations represented by such statements are reasonable, there can be no assurance that a forward-looking statement herein will prove to be accurate.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Entheon to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others: the risk that the Transaction will not realize anticipated benefits, a change in shareholder influence as a result of the Transaction, decline in the share price of Entheon as a result of the Transaction, no regulatory authority has passed on the merits of the Transaction; reliance upon key management and key scientific advisors; adverse consumer perception of psychedelic drugs; adverse and unanticipated clinical study results; changes and unanticipated delays in the regulatory approval process; increased competition in the psychedelic therapy market; adverse changes in general economic conditions; litigation risk; reputational damage; risk that Entheon will be unable to meet its obligations under financial instruments; conflicts of interest; significant ownership and control by significant shareholders; no dividends; requirement for additional financing; that costs and administrative burden of securities law compliance; discretion in the use of unallocated funds; fluctuations in the price of the Common Shares; potential dilution from the exercise of convertible securities; and dilution from additional financings, all as more particularly described in "*Risk Factors*".

Although Entheon has attempted to identify important factors that could cause actual results to differ materially, there may be other factors that cause results not to be as anticipated, estimated or intended. Consequently, all forward-looking statements made in this Listing Statement and other documents of Entheon is qualified by such cautionary statements and there can be no assurance that the anticipated results or developments will actually be realized or, even if realized, that they will have the expected consequences to or effects on Entheon. The cautionary statements contained or referred to in this section should be considered in connection with any subsequent written or oral forward-looking statements that Entheon and/or persons acting on its behalf may issue. Entheon undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

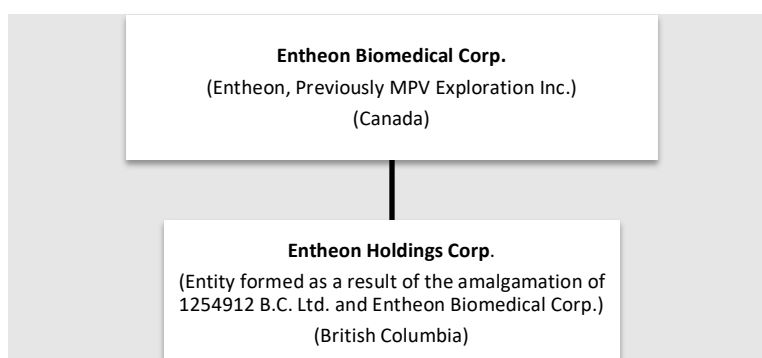
## **2. CORPORATE STRUCTURE**

### **2.1 Overview**

Entheon is a corporation 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, Entheon changed its name to "MPV Exploration Inc." and on November 5, 2020, Entheon changed its name to "Entheon Biomedical Corp." upon completion of the Transaction. The Common Shares are listed for trading on the CSE under the symbol "ENBI". Entheon's registered office is located at located at 595 Howe Street, 10<sup>th</sup> floor, Vancouver, British Columbia, V6C 2T5.

## 2.2 Corporate Structure

Entheon has one wholly-owned subsidiary, Entheon Holdings, a corporation formed as a result of the amalgamation of Subco (1254912 B.C. Ltd.), a British Columbia corporation incorporated on June 26, 2020, pursuant to the BCBCA, solely for the purposes of facilitating the completion of the Amalgamation and Former Entheon, a private British Columbia corporation incorporated on June 17, 2019 pursuant to the BCBCA under the name “Entheogen Biomedical Corp.” On December 30, 2019 Former Entheon changed its name to “Entheon Biomedical Corp.” On November 5, 2020, after the completion of the Amalgamation of Subco and Former Entheon, the amalgamated entity, being Entheon Holdings, changed its name to “Entheon Holdings Corp.” Entheon Holdings’ registered office is located at 595 Howe Street, 10<sup>th</sup> floor, Vancouver, British Columbia, V6C 2T5. The following chart depicts the corporate structure of Entheon:



## 2.3 Fundamental Change

Entheon is requalifying for a listing following a fundamental change, whereby Entheon acquired all of the issued and outstanding Former Entheon Shares pursuant to an arm’s length three-cornered amalgamation with Former Entheon and Subco. On June 30, 2020, Entheon, Former Entheon and Subco entered into the Amalgamation Agreement. In connection with the Transaction and pursuant to the terms of the Amalgamation Agreement: (i) Subco completed the Subco Private Placement; (ii) Entheon completed a name change from “MPV Exploration Inc.” to “Entheon Biomedical Corp.”; (iii) Entheon completed the Consolidation; and (iv) Former Entheon amalgamated with Subco under subsection 269 of the BCBCA to form Entheon Holdings. Entheon Holdings is a wholly-owned subsidiary of Entheon and the Former Entheon Shareholders were issued one Common Share for every one Former Entheon Share held immediately prior to the completion of the Transaction. After completion of the Transaction, Entheon took over the business of Entheon Holdings and although the Transaction resulted in Entheon Holdings becoming a wholly-owned subsidiary of Entheon, the Transaction constituted a reverse take-over of Entheon because the Former Entheon Shareholders now own 73.90% of the outstanding Common Shares. See information under the heading – “*General Development of the Business, The Transaction*” for more information on the Transaction.

## 3. GENERAL DEVELOPMENT OF THE BUSINESS

### 3.1 History

#### Overview of the Business

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 (Dimethyltryptamine) 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**”). It is Entheon’s intention that the DMT Products will be used in medical clinics, treatment centres and hospitals to treat patients with such 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 Dosage 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 a patient for his/her specific addiction. The DMT Products are described in further detail below under the heading “*Narrative Description of the Business – Overview*”

#### *DMT Delivery System*

Furthermore, Entheon eventually seeks to develop and commercialize a set of delivery equipment that can effectively pump its DMT Products into patients and thereafter measure their vital signs to ensure the particular DMT Product is working correctly (the “**DMT Delivery System**”). The DMT Delivery System is described in further detail below under the heading “*Narrative Description of the Business – Overview – DMT Delivery System*”).

Entheon does not currently generate 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.

#### **Historical Developments**

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 (as described in further detail under the heading “*Narrative of the Business – Overview*”).

#### **Summary of the Regulatory Approval Process**

For the purposes of the discussion under this heading and under the heading “*Narrative Description of the Business*,” the following is a high-level overview of the regulatory approval process (the “**Regulatory Approval Process**”) that a biotechnology research and development company typically must go through in order to reach

commercialization. The receipt of regulatory approval 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 Regulatory Approval Process within any expected timeline or at all. Additionally the above Regulatory Approval Process is subject to potential delays, risks, changes and an increase in costs resulting from the on-going COVID-19 pandemic.

## Contracts

Set forth below is a summary of the two arms-length material contracts that Enttheon has entered into as of the date hereof.

- **Psygen Supply Agreement.** Enttheon has entered into the Psygen Supply Agreement whereby Psygen will provide Enttheon 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 Enttheon 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 Enttheon is obliged to pay to Psygen an aggregate of USD\$40,000 (approximately CDN\$53,028 based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257) 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.
- **CHDR Clinical Study Agreement.** Enttheon 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 scheduled to take place in the Netherlands in early 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 Enttheon’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, Enttheon has agreed to: (i) pay CHDR an estimated fee of €927,314 (approx. CDN\$1,430,010 based on the Bank of Canada exchange rate on November 2, 2020 of 1.5421) 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, Enttheon 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.

## Expenditures

As of the date hereof Entheon has expended an aggregate sum of \$265,300 on research and scientific development relating to its DMT Solutions, the DMT Protocol and design of the Phase I Study. In addition, Entheon has expended an aggregate sum of \$68,386 on patent prosecution and portfolio development (as described in detail below). Set forth in the table below is a breakdown of the expenditures made as of September 30, 2020:

| Description of Expenditure                                  | Amount           |
|-------------------------------------------------------------|------------------|
| Literature Review <sup>(1)</sup>                            | \$12,900         |
| Nonclinical Development <sup>(2)</sup>                      | \$25,200         |
| Clinical Development <sup>(3)</sup>                         | \$71,900         |
| Development Efforts <sup>(4)</sup>                          | \$106,900        |
| Regulatory Strategy <sup>(5)</sup>                          | \$48,400         |
| Patent Prosecution and Portfolio Development <sup>(6)</sup> | \$68,386         |
| <b>Total</b>                                                | <b>\$333,686</b> |

- (1) 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), in each case as discussed further under the heading "*Narrative of the Business – Overview*". **Of the \$12,900 expended, \$10,300 was paid to non-arm's length parties and \$2,600 was paid to arm's length consultants.**
- (2) Nonclinical development efforts included: (i) identifying and partnering with Psygen, a GMP licensed and accredited drug manufacturer, 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. **Of the \$25,200 expended, \$5,400 was paid to Entheon's arm's length Science Advisors, \$17,200 was paid to non-arm's length parties and \$2,600 was paid to arm's length consultants.**
- (3) 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. **Of the \$71,900 expended, \$42,800 was paid to Enttheon’s arm’s length Science Advisors, \$14,900 was paid to non-arm’s length parties and \$14,200 was paid to arm’s length consultants.**

- (4) 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 Enttheon’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 Enttheon’s product Investigator Brochure. **Of the \$106,900 expended, \$13,350 was paid to Enttheon’s arm’s length Science Advisors, \$17,200 was paid to non-arm’s length parties and \$76,350 was paid to arm’s length consultants.**
- (5) Because a deep understanding of the regulatory framework in multiple jurisdictions (FDA, EMA, and Health Canada) is necessary for efficiently obtaining drug product approvals, Enttheon has engaged regulatory experts from its earliest stages in order to identify roadblocks and prepare itself to move efficiently through each regulatory system. Enttheon has also expended financial resources on working with its Science Advisors to develop a specific regulatory strategy in the European Union. Lastly, Enttheon has expended financial resources on the development of major regulatory documents including: (i) the Investigational Medicinal Product Dossier; (ii) the Investigator’s Brochure; and (iii) the Drug Master File, all of which are explained in further detail under the heading “3. General Development of the Business – Summary of the Regulatory Approval Process” and all of which are currently under development by Enttheon’s expert consultants, advisors, and clinical partners as part of the lead-up to the Phase I Study. **Of the \$48,400 expended, \$19,750 was paid to Enttheon’s arm’s length Science Advisors, \$14,900 was paid to non-arm’s length parties and \$13,750 was paid to arm’s length consultants.**
- (6) Enttheon has expended financial resources of patent prospection including with respect to: (i) the filing of four provisional patent applications with the United State Patent and Trademark Office relating to Enttheon’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, Enttheon has expended financial resources on portfolio development which consists of the exploration of new technologies using novel compounds and alternative methods of administration. **\$68,386 was paid in legal fees to arm’s length legal counsel.**

The following table sets forth the revenues of Enttheon for the fiscal years ended March 31, 2019 and 2020.

|         | For the fiscal year ended March 31,<br>2019<br>(Audited) | For the fiscal year ended March 31,<br>2020<br>(Audited) |
|---------|----------------------------------------------------------|----------------------------------------------------------|
| Revenue | Nil                                                      | Nil                                                      |

### 3.2 Expected Changes

Enttheon intends to move forward in carrying out its strategies, meeting its business objectives and developing its business as described elsewhere in this Listing Statement – see information under the heading “Narrative of the Business” for a description of Enttheon’s business. However, Enttheon’s strategies and business objectives may be impacted by changes in the global economy, the impact of COVID-19 on Enttheon’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.

### **3.3 Significant Acquisitions and Dispositions**

Apart from the Transaction, Entheon has not completed any significant acquisitions or dispositions in the past three years.

### **3.4 The Transaction**

#### **General**

Entheon is requalifying for a listing following a fundamental change on November 5, 2020, whereby Entheon acquired all of the issued and outstanding Former Entheon Shares by way of a three-cornered arm's length amalgamation with Former Entheon and Subco pursuant to the Amalgamation Agreement. In connection with the Transaction and pursuant to the terms of the Amalgamation Agreement: (i) Subco completed the Subco Private Placement (as described in detail below); (ii) Entheon completed a name change from "MPV Exploration Inc." to "Entheon Biomedical Corp."; (iii) Entheon completed the Consolidation; and (iv) Former Entheon amalgamated with Subco under subsection 269 of the BCBCA to form Entheon Holdings. Thereafter, Entheon Holdings became a wholly-owned subsidiary of Entheon. In accordance with the Amalgamation Agreement, the Former Entheon Shareholders were issued one Common Share for every one Former Entheon Share held immediately prior to the completion of the Transaction. All outstanding Entheon Warrants were adjusted such that, upon exercise or conversion, the holders will receive Common Shares in lieu of Former Entheon Shares, subject to the Exchange Ratio.

#### **The Subco Private Placement**

In connection with the Transaction, Entheon, through Subco, completed the Subco Private Placement on September 3, 2020, pursuant to which Subco issued an aggregate of 4,117,886 Subco Subscription Receipts at a price of \$0.375 per Subco Subscription Receipt for gross proceeds of \$1,544,207.

Upon the satisfaction of certain release conditions, including receipt of CSE approval for the Transaction, each Subco Subscription Receipt was exchanged, 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 Subco Financing 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 Subco Subscription Receipts were converted into Subco Units. In connection with the Subco Private Placement, Subco 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 Broker Warrants, which are exercisable to acquire one 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 Broker Warrant Unit is comprised of one Subco Class A Share and one half of one Underlying Broker 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 Subco Subscription Receipts were converted into Subco Units. Concurrently with the completion of the Transaction: (i) all of the issued and outstanding Subco Class A Shares were exchanged for Common Shares; (ii) all Subco Financing Warrants were exchanged for MPV Financing Warrants; and (iii) all Broker Warrants were exchanged for Replacement Broker Warrants based on the Subco Broker Exchange Ratio.

Entheon intends to use the net proceeds from the Subco Private Placement to carry out its preclinical and human proof of concept studies determining safety, tolerability and dose finding specific to DMT in the treatment of addictive disorders and for general working capital purposes.

As a result of the Transaction, Entheon issued:

- a) an aggregate of 29,845,805 Common Shares in exchange for the Former Entheon Shares outstanding immediately prior to the closing of the Transaction at a deemed issue price of \$0.48 (after taking into effect the Consolidation);
- b) an aggregate of 4,217,886 Common Shares in exchange for the Subco Class A Shares outstanding immediately prior to the closing of the Transaction at a deemed issue price of \$0.48 (after taking into effect the Consolidation);
- c) 2,108,943 MPV Financing Warrants in exchange for the Subco Financing Warrants outstanding immediately prior to the closing of the Transaction; and
- d) 211,297 Replacement Broker Warrants in exchange for the Broker Warrants outstanding immediately prior to the closing of the Transaction.

Although the Transaction resulted in Entheon Holdings becoming a wholly-owned subsidiary of Entheon, the Transaction constituted a reverse take-over of Entheon because: (i) the Former Entheon Shareholders now own 73.90% of the outstanding Common Shares, the former shareholders of Entheon now own 15.66% of the outstanding Common Shares, and the holders of the Subco Subscription Receipts now own 10.44% of the outstanding Common Shares; (ii) the business of Entheon Holdings became the business of Entheon; and (iii) all members of the Entheon Board are designees of Former Entheon. After completion of the Transaction, Entheon changed its name from "MPV Exploration Inc." to "Entheon Biomedical Corp."

### **3.5 Trends, Commitments, Events and Uncertainties**

The following is a discussion of the trends, market outlook and uncertainties related to Entheon's business.

#### **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 under the heading "*Competitive Conditions and Industry Trends.*"

#### **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<sup>1</sup>, 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<sup>2</sup> (the 3rd leading preventable cause of death in the U.S.), while globally 3.3 million deaths, or 5.9 percent of all global deaths, were attributed to alcohol consumption<sup>3</sup>.
- 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<sup>4</sup>.
- 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<sup>5</sup>, 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<sup>6</sup>. 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<sup>7</sup>. *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<sup>8</sup>.
- 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<sup>9</sup>, 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<sup>10</sup>.
- 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<sup>11</sup>, and 480,000 annual deaths are “caused” by smoking<sup>12</sup>. The World Health Organization believes the global financial burden imposed by cigarette consumption and addiction to be well over one trillion dollars<sup>13</sup>.

---

<sup>1</sup> National Institute on Alcohol Abuse and Alcoholism.

<sup>2</sup> 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*.

<sup>3</sup> World Health Organization (WHO). *Global Status Report on Alcohol and Health*. p. XIV. 2014 ed.

<sup>4</sup> 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.

<sup>5</sup> Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health, pg.50.

<sup>6</sup> <https://www.who.int/news-room/fact-sheets/detail/opioid-overdose>.

<sup>7</sup> *Medications to Treat Opioid Use Disorder Research Report*. National Institute on Drug Abuse. Research report, Revised June 2018.

<sup>8</sup> *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.

<sup>9</sup> 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.

<sup>10</sup> 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.

<sup>11</sup> [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/effects\\_cig\\_smoking/](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/)

<sup>12</sup> 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.

<sup>13</sup> <https://www.who.int/tobacco/economics/background/en/>.

This combination of an under-served 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<sup>14</sup>. 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<sup>15</sup>; (ii) Compass Pathways is in phase 2 with psilocybin to treat treatment resistant depression<sup>16</sup>; and (iii) the Usona Institute is in a phase 2 study focusing on the use of psilocybin for major depressive disorder<sup>17</sup>.

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<sup>18</sup>. 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 will also be submitting a decriminalization initiative (Initiative 81) on the ballot of upcoming election on November 3, 2020<sup>19</sup>.

## Uncertainties

There are a number uncertainties and risks that are presently known to management that could reasonably be expected to have a material effect on Entheon’s business. See information under the heading “*Risk Factors*” for a full description of the risks and uncertainties related to Entheon and its business.

## 4. NARRATIVE DESCRIPTION OF THE BUSINESS

### 4.1 Overview

As discussed above under the heading “*General Development of the Business – Overview of the Business*,” Entheon is a biotechnology research and development company committed to developing and commercializing both its DMT Products and its DMT Delivery System for the purposes of treating addiction and substance use disorders. 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.

#### DMT Products

---

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

<sup>15</sup> <https://clinicaltrials.gov/ct2/show/NCT03537014>

<sup>16</sup> <https://clinicaltrials.gov/ct2/show/NCT03775200>

<sup>17</sup> <https://clinicaltrials.gov/ct2/show/NCT03866174>

<sup>18</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified>

<sup>19</sup> [https://ballotpedia.org/Washington,\\_D.C.,\\_Initiative\\_81,\\_Entheogenic\\_Plants\\_and\\_Fungus\\_Measure\\_\(2020\)](https://ballotpedia.org/Washington,_D.C.,_Initiative_81,_Entheogenic_Plants_and_Fungus_Measure_(2020)).

As discussed under the heading “*General Development of the Business – DMT Products*” Entheon seeks to develop and commercialize a portfolio of safe and effective DMT Products. The DMT Products will consist of proprietary DMT drug formulations packaged in single-use containers. These containers may alternatively take the form of intravenous bags, ampules, or cartridges but in any case will be designed to work within the DMT Delivery System (see below). Each unit of the DMT based drug solution will be offered in tamper-proof packaging and sealed in a way that only allows it to be used for one treatment session. The contents will be a proprietary mixture and will include the exact amount of DMT for the treatment in 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 “*Research and Development Studies*.” 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.

#### *DMT Delivery System*

Additionally, Entheon seeks to eventually develop and commercialize the DMT Delivery System to administer its DMT Products and ensure their accurate performance (as described in further detail below under the heading “*Technology - DMT Delivery System*”). Entheon intends to develop the DMT Delivery System such that it will slowly pump its DMT Products into patients and thereafter, measure their vital signs to ensure the particular DMT Product is working correctly. This equipment will use a proprietary interface to connect the container of DMT-based solution (described above) to a special intravenous pump that will be optimized to deliver the DMT Products according to their particular Dosing Strategies. 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.

#### **Development Efforts to Date**

##### *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 Product 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.

## 4.2 Business Objectives

### Milestones and Business Objectives

Set forth below are Entheon's milestones, expected target dates and associated costs over the next twelve months. A detailed discussion of each of these milestones is set forth under the heading "*Research and Development Studies*."

| Milestone                                                                   | Target Date                  | Estimated Cost                                         |
|-----------------------------------------------------------------------------|------------------------------|--------------------------------------------------------|
| Obtaining the Drug Products from Psygen for nonclinical and clinical trials | November 2020                | USD\$40,000 (approx. CDN\$53,028) <sup>(1)</sup>       |
| Meet with Netherlands Dutch Regulators                                      | December 2020                | \$30,000                                               |
| Conducting the Preclinical Studies                                          | January 2021 to June 2021    | USD\$66,500 (approximately CDN\$88,159) <sup>(1)</sup> |
| DMT formulation development                                                 | January 2021 to October 2021 | \$70,000 <sup>(2)</sup>                                |
| Stability testing of drug substance and drug product                        | January 2021                 | \$20,000                                               |
| DMT Assay Development                                                       | January 2021 to June 2021    | \$100,000                                              |
| Obtain Clinical Trial Insurance                                             | March 2021                   | \$50,000                                               |
| Developing the DMT Protocol and Conducting the Phase I Study                | April 2021 to September 2021 | €927,314 (approx. CDN\$1,430,010) <sup>(3)</sup>       |
| <b>Total</b>                                                                |                              | <b>\$1,841,197</b>                                     |

<sup>(1)</sup> Based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257.

<sup>(2)</sup> Estimated cost of \$70,000 in the next 12 months and an additional ongoing cost of \$260,000 to the end of 2024.

<sup>(3)</sup> Based on the Bank of Canada exchange rate on November 2, 2020 of 1.5421.

Although the target dates and estimated costs set forth in the table above are Entheon's best estimates, such dates and costs may be impacted by a number of factors, including without limitation, those discussed under the

heading “Expected Changes”. There is no guarantee that Entheon will obtain the regulatory approvals required to meet the milestones set out in the table above, within the timeframes and at costs anticipated, or at all.

### 4.3 Funds Available

The following is a breakdown of the funds that are available to Entheon (the “Available Funds”) as of September 30, 2020, the most recent month end prior to filing this Listing Statement:

| Source of Funds                                    | Available Funds    |
|----------------------------------------------------|--------------------|
| Working capital of Entheon <sup>(1)</sup>          | \$981,201          |
| Working capital of Entheon Holdings <sup>(2)</sup> | \$1,595,018        |
| Proceeds of Subco Private Placement <sup>(3)</sup> | \$1,544,207        |
| Proceeds from sale of property <sup>(4)</sup>      | \$278,000          |
| <b>Total</b>                                       | <b>\$4,398,426</b> |

<sup>(1)</sup> As at October 31, 2020.

<sup>(2)</sup> As at October 31, 2020.

<sup>(3)</sup> Represents the approximate gross proceeds of the Subco Private Placement.

<sup>(4)</sup> It was condition to closing the Transaction that Entheon assign or dispose of all existing mineral resource properties, including Entheon’s rights under the option agreement dated March 31, 2017 between Entheon and Les Ressources Tectonic Inc. as it relates to the UMEX project. In connection therewith, Entheon entered into a binding agreement following a tender process on August 5, 2020 pursuant to which it agreed to sell its interest in the UMEX project for cash consideration of \$278,000. The funds were held in escrow with Dunton Rainville pending completion of the Transaction.

### 4.4 Principal Purposes

The following table sets out the principal purposes for which the Available Funds available will be used by Entheon.

| Use of Available Funds                                                                      | Amount                                                 |
|---------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <b>Estimated available funds</b>                                                            | <b>\$4,398,426</b>                                     |
| Obtaining the Drug Products from Psygen for nonclinical and clinical trials                 | USD\$40,000 (approx. CDN\$53,028) <sup>(1)</sup>       |
| Meeting with Netherlands Dutch Regulators                                                   | \$30,000                                               |
| Conducting the Preclinical Studies                                                          | USD\$66,500 (approximately CDN\$88,159) <sup>(1)</sup> |
| DMT formulation development                                                                 | \$70,000                                               |
| Stability testing of drug substance and drug product                                        | \$20,000                                               |
| DMT Assay Development                                                                       | \$100,000                                              |
| Clinical Trial Insurance                                                                    | \$50,000                                               |
| Developing the DMT Protocol and Conducting the Phase I Study                                | €927,314 (approx. CDN\$1,430,010) <sup>(2)</sup>       |
| Operating expenses for 12 months <sup>(3)</sup>                                             | \$1,932,000                                            |
| Legal, administrative, regulatory fees expended for Transaction and Subco Private Placement | \$438,334                                              |
| <b>Total</b>                                                                                | <b>\$4,211,531</b>                                     |
| <b>Unallocated Working Capital</b>                                                          | <b>\$186,895</b>                                       |

<sup>(1)</sup> Based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257.

<sup>(2)</sup> Based on the Bank of Canada exchange rate on November 2, 2020 of 1.5421. In accordance with the CHDR Clinical Study Agreement 21% of this figure has been reserved for potential COVID-related costs.

- (3) Estimated operating expenses for 12 months include: \$800,000 for corporate branding and advertising, \$48,000 for marketing and promotion, \$150,000 for Directors & Officers insurance, \$372,000 for management fees, \$328,000 for consulting fees, \$78,000 for office expense and rent and \$156,000 for professional legal and accounting fees.

Entheon intends to spend its Available Funds as stated in this Listing Statement. However, there may be circumstances where, for sound business reasons, a reallocation of funds may be necessary.

#### 4.5 Research and Development Studies

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.

##### Timing, Costs, Stage of Development & Major Components of Proposed Studies

As discussed in further detail under the heading "*Intellectual Property – 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 "*Expected Changes*"):

- 1. Sourcing the Drug Products.** Entheon has entered into the Psygen Supply Agreement whereby Psygen 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 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 Entheon is obliged to pay to Psygen an aggregate of USD\$40,000 (approximately CDN\$53,028 based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257) 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. Meeting with Dutch Regulators.** Entheon will need to meet with drug regulators in the Netherlands to discuss the Phase I Study design, the DMT Protocol and DMT historical data to determine if further animal data is required. Meetings with the appropriate regulatory authorities will be essential for achieving Entheon's business goals. Entheon will meet with the Dutch regulators being the Central Committee on Research Involving Human Subjects (an organization established under the Dutch *Medical Research Involving Subjects Act*, "**CCMO**") and the EMA, to discuss the regulatory path forward, identify gaps in preclinical data and to get guidance on the trial design in order to maximize the possibility of obtaining regulatory approval. Entheon expects that this will cost approximately \$30,000 and occur in December 2020.

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 not entered into any agreement with any particular CRO but is still confirming which CRO it wishes to work with, the location where the Preclinical Studies will take place and the details of the particular Preclinical Study agreement to be entered into. Entheon is currently evaluating several candidate CROs in Canada, 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 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 studies of acute intravenous toxicity in rats for USD\$14,000 (approx. CDN\$18,559) and cardiovascular toxicity in dogs for USD\$52,500 (approx. CDN\$69,599) for a total of approx. CDN\$88,159 (based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257).
  - **Objectives:** to 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 will only be comprised of *In vivo* (on a living organism) studies. Further the *In vivo* studies are expected to be minimally necessary and limited to an acute intravenous toxicity study in rats and a cardiovascular safety pharmacology study in dogs. 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. *In vitro* (outside a living organism) studies are also not expected to be necessary. 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 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. 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, Enttheon 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, targeted for December 2020. Estimated cost is \$50,000.
8. **Developing a Clinical DMT Protocol and Conducting the Phase I Study.** Enttheon 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 Enttheon's DMT Protocol. In connection therewith, Enttheon has entered into the CHDR Clinical Study Agreement to perform the Phase I Study scheduled to take place in the Netherlands in early 2021, subject to the delays discussed under the heading "*Expected Changes*" 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 "*3. General Development of the Business – History – Overview of the Business – Contracts.*"
  - **Cost:** Enttheon has agreed to pay CHDR an estimated fee of €927,314 (approx. CDN\$1,430,010 based on the Bank of Canada exchange rate on November 2, 2020 of 1.5421) for completion of the Phase I Study.
  - **Description:** It is very important for Enttheon 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 Enttheon'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 Enttheon'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 "*Expected Changes.*" The following additional steps are required to fully develop and commercialize the DMT Products for the purposes of treating nicotine

addition. Subject to any impact that COVID-19 may have on Enttheon's personnel and business operations, no additional costs will be incurred for this work as it is to be performed internally and therefore is already captured by the operating expenses set forth under the "Use of Available Funds" table above.

- **Preparing Submissions to Regulators.** Enttheon is preparing certain regulatory documentation to submit to: (a) the FDA; (b) the EMA; and (c) Health Canada. The relevant documents that Enttheon is in the process of preparing take the form of an IMPD and Investigator's Brochure. As discussed in further detail under the heading "*General Development of the Business – Summary of the Regulatory Approval 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 Enttheon'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 Enttheon'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 "*Expected Changes*." Enttheon will require additional sources of financing in order to fund the steps set forth below.

- **Meeting with FDA.** Enttheon 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 Enttheon 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;
- **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, Enttheon 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.
- **Licensing of DMT for Nicotine Addiction.**

## 4.6 Technology

### DMT Delivery System

As discussed under the heading “*Narrative Description of the Business – Overview*,” Entheon’s intends to develop a DMT Delivery System to administer its DMT Products 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 “*Proposed Method of Production & Development*,” 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.

## 4.7 Proposed Method of Production & Development

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 “*Narrative Description of the Business – Research and Development Studies – Timing, Cost, Stage of Development & Major Components of Proposed Studies*,” Entheon has entered into the Psygen Supply Agreement, whereby Psygen will supply the Drug Products (both GMP quality and non-GMP DMT drug products) and substances (for 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 (approximately CDN\$53,028 based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257) 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. 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 “*Narrative Description of the Business – Technology – 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 (U.S.), B. Braun Melsungen AG (Germany), and Baxter International Inc. (U.S.). The IPS will enable Enttheon to provide controlled, consistent and continuous drug delivery of Enttheon’s DMT Products.

#### 4.8 Lease

Enttheon and Hyperlaunch Investments Inc. (the “**Landlord**”) have entered into a rental lease agreement (“**Lease Agreement**”). The term of the Lease Agreement is for a period of one (1) year, beginning on August 1, 2020 and ending on July 31, 2021. At the end of the term, the Lease Agreement will automatically renew on a month to month basis and may be terminated by thirty (30) days written notice given by either party. The rent to be paid by Enttheon to the Landlord throughout the term of the Lease Agreement is \$4,000 per month plus applicable taxes.

#### 4.9 Specialized Skill and Knowledge

Pursuant to certain consultant agreements, in order to assist in the development of its DMT Solutions and the DMT Protocol, Enttheon 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 Enttheon’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 UBC 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 CAD \$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 U.S., European Union, Israeli and Australian regulatory agencies including the registration of manufacturing facilities in the U.S., Central America, Israel and Australia to Good Manufacturing Practice levels. Yaron has led clinical trials in the U.S., 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 CAD \$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 Enttheon’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 Enttheon Board by the mutual agreement of Enttheon and Dr. Gondi; (C) the removal of Dr. Gondi from the Enttheon Board by the

shareholders of Enttheon in the manner prescribed by the CBCA; and (D) the resignation by Dr. Gondi from the Enttheon Board. The agreement which among other things, contains non-competition, non-solicitation and non-disclosure provisions. Compensation under the agreement includes a fee of CAD \$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 (approx. CDN\$7,291 based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257) per fiscal quarter.
- **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.

#### 4.10 Sources, Pricing and Technology

As discussed in further detail above under the heading “*Narrative Description of the Business – Research and Development Studies – Timing, Cost, Stage of Development & Major Components of Proposed Studies,*” Entheon has entered into the Psygen Supply Agreement, whereby Psygen will supply the Drug Products (both GMP quality and non-GMP DMT drug products and substances) for preclinical, clinical, and post-approval commercialization phases under the European regulatory framework. As set forth in the table below, under the Psygen Supply Agreement, Entheon is obliged to pay to Psygen an aggregate of USD\$40,000 (approximately CDN\$53,028 based on the Bank of Canada exchange rate on November 2, 2020 of 1.3257) 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.

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

- (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.

#### 4.11 Intellectual Property

##### 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

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.
- 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.
- 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.

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.

#### **4.12 Seasonality**

The business of Entheon is not subject to seasonality fluctuations.

#### **4.13 Renegotiation or Termination of Contracts**

Entheon does not anticipate its business will be affected by renegotiation or termination of contracts or subcontracts during the current financial year.

#### **4.14 Environmental Protection**

Entheon does not believe there are any current or future environmental protection requirements that will have a material impact on capital expenditures, earnings, or competitive position.

#### **4.15 Employees**

Entheon has 3 full-time employees and 16 consultants and part-time contractors.

#### **4.16 Regulatory Regimes and Foreign Operations**

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, N,N-Dimethyltryptamine (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, Enttheon 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 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***

#### ***CDSA***

In order to conduct any scientific research, including pre-clinical (animal) and clinical (human) trials using a controlled substance (such as DMT) in Canada, an exemption under Section 56 of the CDSA is required. This exemption allows the holder to possess and use the controlled substance without being subject to the restrictions set out in the CDSA, 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.

#### ***Canada FDR***

Products that contain a controlled substance such as DMT cannot be made, transported or sold without proper authorization from the government. A party can apply for a dealer's license under Part J of the Canada Food and Drug Regulations ("**Canada FDR**"), which 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 United 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.

## **Regulatory Approval Strategy**

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 "*Expected Changes*"), 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 below, Entheon intends to engage Health Canada and FDA to identify the most efficient path toward trial approval.

## **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. Enttheon 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 "*Expected Changes.*"

#### *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 U.S. 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 “*Expected Changes.*”

#### *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 Enttheon 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 U.S. 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 will occur in the Netherlands for 2021 and the current focus is preparing an IMPD document that includes CMC (Chemistry, Manufacturing and Control) information, an Investigator's Brochure (including prior safety, preclinical and clinical data) and a clinical study protocol and supporting information to be submitted to Dutch regulatory authorities, all of which is subject to the risks, delays and related cost implications discussed under the heading "*Expected Changes*". In the Netherlands, this agency is the CCMO (aka the Central Committee on Research Involving Human Subjects). These documents will be co-developed in collaboration with the CHDR in Leiden, the site of the proposed clinical study, and a pre-submission meeting with CCMO is planned for December 2020.

#### *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.

#### 4.17 Significant Contracts

Set forth below is a description of the agreements upon which Enttheon's business is substantially dependent:

- **Psygen Supply Agreement** – pursuant to the Psygen Supply Agreement, Psygen will provide Enttheon with both GMP quality and non-GMP DMT drug products and substances for its preclinical, clinical and post-approval commercialization phases under the European regulatory framework as discussed in further detail above under the headings *“General Development of the Business – History – Contracts”* and *“Narrative Description of the Business – Research and Development Studies – Timing, Cost, Stage of Development & Major Components of Proposed Studies;”* and
- **CHDR Clinical Study Agreement** – pursuant to the CHDR Clinical Study Agreement, Enttheon has engaged CHDR to perform the Phase I Study scheduled to take place in early 2021, as discussed in further detail above under the headings *“General Development of the Business – History – Contracts”* and *“Narrative Description of the Business – Research and Development Studies – Timing, Cost, Stage of Development & Major Components of Proposed Studies”*.

#### 4.18 Market Segments and Geographic Areas

Subject to receiving the applicable FDA, Health Canada and EMA approvals, Enttheon intends to operate in the United States, Canada and different countries in the European Union.

#### 4.19 Competitive Conditions and Industry Trends

Enttheon 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 Enttheon's largest competitors.

- **Mind Medicine (MindMed) Inc.** – is 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 Enttheon 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 private mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health. The company, like Enttheon is focused on the clinical trial pathway, but is tackling a different indication being resistant depression and utilizing a different psychedelic molecule being psilocybin. The company received “Breakthrough Therapy” designation from the FDA in 2018 and are presently conducting randomized controlled phase 2 studies<sup>20</sup> of psilocybin therapy, testing safety and efficacy of psilocybin in participants with treatment resistant depression<sup>21</sup>.
- **Small Pharma** – is a United Kingdom based private company focused on creating novel psychedelic formulations for the treatment of clinical depression. The company has close ties with academia and plans

---

<sup>20</sup> 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.

<sup>21</sup> <https://clinicaltrials.gov/ct2/show/NCT03775200>.

to identify opportunities lost in the development process and revitalize them. The company, at present, is researching DMT as a molecule, 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.

#### 4.20 Bankruptcy and Similar Procedures

Entheon does and has not had any bankruptcy (whether voluntary or otherwise), receivership or other similar proceedings instituted by it or against it since its incorporation nor are any such proceedings being contemplated or threatened in the foreseeable future.

#### 4.21 Material Restructuring Transactions

Other than the Transaction, Entheon has not completed any material restructuring transactions since incorporation.

### 5. SELECTED CONSOLIDATED FINANCIAL INFORMATION

#### 5.1 Consolidated Financial Information – Annual Information

Entheon's financial statements for the fiscal years ended March 31, 2020 (audited) and March 31, 2019 (audited) are attached as Schedule "A" hereto.

The following selected financial information is subject to the detailed information contained in the financial statements of Former Entheon and related notes included in this Listing Statement. The selected financial information is derived from and should be read in conjunction with the Former Entheon unaudited financial statements as at and for the nine month period ended August 31, 2020 and the Former Entheon audited financial statements as at and for the period from incorporation on June 17, 2019 to November 30, 2019 attached as Schedule "E" hereto.

|                                            | As at and for the nine month<br>period ended August 31, 2020<br>(Unaudited)<br>(\$) | As at and for the period from<br>incorporation on June 17, 2019 to<br>November 30, 2019<br>(Audited)<br>(\$) |
|--------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Revenue                                    | Nil                                                                                 | Nil                                                                                                          |
| Total Expenses                             | 1,127,026                                                                           | 278,028                                                                                                      |
| Other income                               | Nil                                                                                 | Nil                                                                                                          |
| Net Loss                                   | 1,061,062                                                                           | 278,028                                                                                                      |
| Basic and Diluted<br>Loss per Share        | 0.04                                                                                | 0.07                                                                                                         |
| Current Assets                             | 1,924,880                                                                           | 136,866                                                                                                      |
| Total Assets                               | 2,036,394                                                                           | 136,866                                                                                                      |
| Current Liabilities                        | 44,115                                                                              | 94,692                                                                                                       |
| Total Liabilities                          | 44,115                                                                              | 94,692                                                                                                       |
| Total Shareholders' Equity<br>(Deficiency) | 1,992,279                                                                           | 42,174                                                                                                       |

There were no material changes in the Former Entheon's business or operations that affected the variations in each period in the data above. See notes to the applicable financial statements for a further discussion.

## 5.2 Consolidated Financial Information – Quarterly Information

The following table sets out certain selected consolidated financial information of Enttheon for the eight most recently completed quarters ended at the end of the most recently completed financial year.

|                          | Three months Sept 30, 2018 | Three months ended Dec 31, 2018 | Three months ended March 31, 2019 | Three months ended June 30, 2019 | Three months ended Sept 30, 2019 | Three months ended Dec 31, 2019 | Three months ended March 31, 2020 | Three months ended June 30, 2020 |
|--------------------------|----------------------------|---------------------------------|-----------------------------------|----------------------------------|----------------------------------|---------------------------------|-----------------------------------|----------------------------------|
| <b>Statement of Loss</b> |                            |                                 |                                   |                                  |                                  |                                 |                                   |                                  |
| Revenue                  | Nil                        | Nil                             | Nil                               | Nil                              | Nil                              | Nil                             | Nil                               | Nil                              |
| Expenses                 | 39,906                     | 62,646                          | 83,622                            | 48,512                           | 23,053                           | 54,259                          | 40,961                            | 335,922                          |
| Other Items              | (3,297)                    | (4,046)                         | (3,904)                           | (4,998)                          | (4,988)                          | (4,936)                         | (5,080)                           | (13,906)                         |
| <b>Net Losses</b>        | <b>36,609</b>              | <b>58,600</b>                   | <b>79,718</b>                     | <b>43,514</b>                    | <b>18,065</b>                    | <b>49,323</b>                   | <b>35,881</b>                     | <b>322,016</b>                   |

Enttheon Holdings has not been a reporting issuer for the eight most recently completed quarters ended at the end of the most recently completed financial year and has not prepared quarterly financials for all such periods.

## 5.3 Dividends

There are no restrictions that would prevent Enttheon from paying dividends on the Common Shares, however, Enttheon has neither declared nor paid any dividends on the Common 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 Enttheon Board. The payment of dividends will depend upon Enttheon's earnings, its capital requirements and its financial condition, as well as other relevant factors. Enttheon intends to retain its earnings to finance growth and expand its operations and does not anticipate paying any dividends on the Common Shares in the foreseeable future.

## 5.4 International Financial Reporting Standards.

The financial statements of Enttheon and of Enttheon Holdings have been prepared in accordance with International Financial Reporting Standards.

## 6. MANAGEMENT'S DISCUSSION AND ANALYSIS

Enttheon's Management's Discussion and Analysis provides an analysis of Enttheon's financial results for the fiscal years ended March 31, 2019 and 2020 and for the three month period ended June 30, 2020 and should be read in conjunction with the condensed consolidated annual financial statements of Enttheon for such periods, and the respective notes thereto. Enttheon's Management's Discussion and Analysis' are attached to this Listing Statement as Schedule "B" and Schedule "D".

Former Enttheon' Management's Discussion and Analysis provides an analysis of Former Enttheon' financial results for the period from incorporation on June 17, 2019 to November 30, 2019, and the nine months ended August 31, 2020 and should be read in conjunction with the condensed consolidated annual and interim financial statements of Former Enttheon for such periods, and the respective notes thereto. Former Enttheon' Management's Discussion and Analysis is attached to this Listing Statement as Schedule "D".

## 7. MARKET FOR SECURITIES

The Common Shares are listed for trading on the CSE under the symbol “ENBI.” The Common Shares were first listed for trading on May 3, 2018 and were halted on July 2, 2020 prior to the announcement and pending completion of the Transaction.

## 8. CONSOLIDATED CAPITALIZATION

### 8.1 Pro Forma Consolidated Capitalization

The following table sets forth the capitalization of Entheon as at March 31, 2020, the most recently completed financial year end and the capitalization of Entheon as of the date hereof.

|                             | As at March 31, 2020 |                           | As of the Date Hereof               |                           |
|-----------------------------|----------------------|---------------------------|-------------------------------------|---------------------------|
| Designation of Security     | Amount Authorized    | Amount Outstanding        | Amount Authorized                   | Amount Outstanding        |
| Common Shares               | Unlimited            | 18,105,514 <sup>(1)</sup> | Unlimited                           | 40,388,851 <sup>(2)</sup> |
| Options                     | 10% of Common Shares | 1,610,000                 | 10% of Common Shares <sup>(3)</sup> | Nil                       |
| Warrants                    | N/A                  | 13,958,933                | N/A                                 | 11,124,822 <sup>(4)</sup> |
| Replacement Broker Warrants | N/A                  | N/A                       | N/A                                 | 316,945 <sup>(5)</sup>    |

<sup>(1)</sup> Numbers are presented on a pre-Consolidation and non-diluted basis.

<sup>(2)</sup> Numbers are presented on a post-Consolidation and non-diluted basis.

<sup>(3)</sup> The number of stock options that Entheon may grant will be limited by the terms of the Stock Option Plan and policies of the CSE.

<sup>(4)</sup> Exercisable into Common Shares at prices ranging from \$0.45, \$0.48, \$0.50, \$0.60, \$0.75 and \$0.90 per share and having expiry dates ranging from December 4, 2020 to November 5, 2022.

<sup>(5)</sup> Exercisable into Replacement Broker Warrant Units at an exercise price of \$0.375 for a period of two years from the closing of the Subco Private Placement, with each Replacement Broker Warrant Unit being comprised of one Common Share and one-half of one Underlying Replacement Broker Warrant.

### 8.2 Fully Diluted Share Capital

The following table states the fully diluted share capital of Entheon as of the date hereof:

| Description of Security                                                                           | Number of Securities | % of Total  |
|---------------------------------------------------------------------------------------------------|----------------------|-------------|
| Common Shares                                                                                     | 40,388,851           | 77.92%      |
| Common Shares reserved for issuance on exercise of the Warrants                                   | 11,124,822           | 21.46%      |
| Common Shares reserved for issuance on exercise of the Options                                    | Nil                  | Nil         |
| Common Shares reserved for issuance on the exercise of the Replacement Broker Warrants            | 211,297              | 0.41%       |
| Common Shares reserved for issuance on the exercise of the Underlying Replacement Broker Warrants | 105,648              | 0.20%       |
| <b>Total outstanding securities of Entheon (on a fully diluted basis)</b>                         | <b>51,830,618</b>    | <b>100%</b> |

## **9. OPTIONS TO PURCHASE SECURITIES**

### **9.1 Options**

As of the date hereof there are no Options issued and outstanding.

### **9.2 Option Plan**

In accordance with, and on the terms and conditions of, the Stock Option Plan, Enttheon may from time to time grant Options to employees, directors, senior officers or consultants of Enttheon or of Enttheon Holdings. The Stock Option Plan was approved by shareholders of Enttheon on September 12, 2017. See full description of the Stock Option Plan under the heading “*Executive Compensation – Stock Option Plan.*”

## **10. DESCRIPTION OF SECURITIES**

### **10.1 Authorized and Issued Share Capital**

The authorized share capital of Enttheon consists of an unlimited number of Common Shares. As of the date hereof there are an aggregate of 40,388,851 Common Shares issued and outstanding (on a non-diluted basis) as fully paid and non-assessable common shares in the capital of Enttheon.

The holders of the Common Shares are entitled to receive notice of and to attend and vote at all meetings of the shareholders of Enttheon and each Common Share confers the right to one vote in person or by proxy at all meetings of the shareholders of Enttheon. The holders of the Common Shares, subject to the prior rights, if any, of any other class of shares of Enttheon are entitled to receive such dividends in any financial year as the Enttheon Board may by resolution determine. In the event of the liquidation, dissolution or winding-up of Enttheon, whether voluntary or involuntary, the holders of the Common Shares are entitled to receive, subject to the prior rights, if any, of the holders of any other class of shares of Enttheon, the remaining property and assets of Enttheon.

### **10.2 Other Securities**

No securities other than the Common Shares are being listed.

### **10.3 Prior Sales**

Other than: (i) the Common Shares issued upon the exercise of 870,000 Options immediately prior to Consolidation and the closing of the Transaction; and (ii) the securities issued pursuant to the Transaction (described under the heading “*General Development of the Business – The Transaction*”), in each case as set out below, Enttheon did not issue any securities within the 12 months prior to the date of this Listing Statement.

Immediately prior to the Consolidation and the closing of the Transaction, Enttheon issued: (i) an aggregate of 750,000 Common Shares (on a pre-Consolidation basis) to certain option holders of Enttheon upon the exercise of an aggregate of 750,000 Options at \$0.10 per Common Share; and (ii) an aggregate of 120,000 Common Shares (on a pre-Consolidation basis) to certain option holders of Enttheon upon the exercise of an aggregate of 120,000 Options at \$0.12 per Common Share.

In connection with the Transaction, Enttheon issued:

- a) an aggregate of 29,845,805 Common Shares in exchange for the Former Enttheon Shares outstanding at the closing of the Transaction at a deemed issue price of \$0.48 (after taking into effect the Consolidation);
- b) an aggregate of 4,217,886 Common Shares (inclusive of the 100,000 Subco Class A Shares comprising the Finders’ Units) in exchange for the outstanding Subco Class A Shares issued on the conversion of the Subco

Subscription Receipts at the closing of the Transaction at a deemed issue price of \$0.48 (after taking into effect the Consolidation);

- c) an aggregate of 2,108,943 MPV Financing Warrants (inclusive of the 50,000 Subco Financing Warrants comprising the Finders' Units) in exchange for the outstanding Subco Financing Warrants issued on the conversion of the Subco Subscription Receipts at the closing of the Transaction;
- d) an aggregate of 211,297 Replacement Broker Warrants in exchange for the Broker Warrants outstanding immediately prior to the closing of the Transaction

## 10.4 Stock Exchange Price

The Common Shares are listed on the CSE under the trading symbol "ENBI." The following table shows the high and low trading prices and total trading volume of the Common Shares on the CSE on a monthly basis for the current quarter and the immediately preceding quarter and on a quarterly basis for the next preceding seven quarters.

| Month                            | High               | Low                | Total Volume       |
|----------------------------------|--------------------|--------------------|--------------------|
| Month ended October 31, 2020     | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> |
| Month ended September 30, 2020   | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> |
| Month ended August 31, 2020      | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> |
| Month ended July 31, 2020        | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> | N/A <sup>(1)</sup> |
| Month ended June 30, 2020        | \$0.16             | \$0.15             | 349,500            |
| Month ended May 31, 2020         | \$0.15             | \$0.15             | 100,000            |
| Month ended April 30, 2020       | \$0.14             | \$0.14             | 72,000             |
| Quarter ended March 31, 2020     | \$0.14             | \$0.09             | 530,000            |
| Quarter ended December 31, 2019  | \$0.09             | \$0.07             | 380,000            |
| Quarter ended September 30, 2019 | \$0.15             | \$0.11             | 730,000            |
| Quarter ended June 30, 2019      | \$0.17             | \$0.13             | 850,000            |
| Quarter ended March 31, 2019     | \$0.13             | \$0.12             | 910,000            |
| Quarter ended December 31, 2018  | \$0.09             | \$0.07             | 750,000            |
| Quarter ended September 30, 2018 | \$0.16             | \$0.14             | 540,000            |

<sup>(1)</sup> The Common Shares were halted on July 2, 2020 prior to the announcement and pending completion of the Transaction.

The last closing price of the Common Shares on July 2, 2020, being the last day pre-Consolidation Common Shares traded prior to the announcement of the Transaction was \$0.16.

## 11. ESCROWED SECURITIES

### Escrow Agreement

In accordance with CSE Policy 2, each Escrowed Entheon Shareholder (constituting "Related Persons" as defined in the policies of the CSE) entered into the Escrow Agreement pursuant to which a total of 3,050,001 Common Shares, have been made subject to escrow restrictions over a 36-month period. As Entheon is an "emerging issuer" pursuant to NP 46-201, the following automatic timed releases apply to the Common Shares held by the Escrowed Entheon Shareholders:

| 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 will result 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.

The following table lists, as of the date of this Listing Statement the Escrowed Entheon Shareholders and the corresponding number and percentage of Common Shares that are held in escrow, in each case, pursuant to the terms of the Escrow Agreement:

| Name of Security Holder | Number of Common Shares held in Escrow | % of Class (non-diluted) |
|-------------------------|----------------------------------------|--------------------------|
| Timothy Ko              | 1,300,001                              | 3.22%                    |
| Brandon Schwabe         | 1,250,000                              | 3.09%                    |
| Christopher Gondi       | 500,000                                | 1.24%                    |
| <b>Total</b>            | <b>3,050,001</b>                       | <b>7.55%</b>             |

## 12. PRINCIPAL SHAREHOLDERS

To the knowledge of the directors and senior officers of Entheon, as of the date hereof, no Person beneficially owns, directly or indirectly, or exercises control or direction over, more than 10% of the voting securities.

## 13. DIRECTORS AND OFFICERS

### 13.1 General

The following table provides the names, municipalities of residence, position, principal occupations and the number of voting securities that each director and officer of Entheon beneficially owns, directly or indirectly, or exercise control over, as of the date hereof:

| Name and Municipality of Residence                                | Principal Occupation During Last Five Years                                                                                                         | Position with Entheon                           | Number of Common Shares to be Held | Percentage of Class to be Held or Controlled |
|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------------------|----------------------------------------------|
| Timothy Ko, <sup>(1)</sup><br>Vancouver, British Columbia, Canada | Founder of Former Entheon and Chief Executive Officer of Former Entheon since incorporation<br>Director of Hyperbridge Technology from 2017 to 2019 | President, Chief Executive Officer and Director | 1,300,001                          | 3.22%                                        |

|                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                              |                                    |                  |              |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------|--------------|
|                                                                             | President of Acom Building Maintenance from 2009 to 2017                                                                                                                                                                                                                                                                                                                                                                     |                                    |                  |              |
| Brandon Schwabe<br>CPA, CGA,<br>Vancouver, British<br>Columbia, Canada      | 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                                                                                                                           | Chief Financial Officer            | 1,250,000        | 3.09%        |
| Dr. Andrew Hegle,<br>Vancouver, British<br>Columbia, Canada                 | 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                                                                                                                                                      | Chief Science Officer and Director | 100,000          | 0.25%        |
| Dr. Christopher Gondi, <sup>(1)</sup><br>Dunlap, Illinois,<br>United States | Research Assistant Professor - Departments of Medicine, Surgery and Pathology at the University of Illinois College of Medicine Peoria                                                                                                                                                                                                                                                                                       | Director                           | 500,000          | 1.24%        |
| Ruth Chun, <sup>(1)</sup><br>Campbellville,<br>Ontario, Canada              | 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, Rossing Pension Fund, March 2016 – August 2017 | Director                           | Nil              | Nil          |
| <b>Total</b>                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                              |                                    | <b>3,150,001</b> | <b>7.80%</b> |

<sup>(1)</sup> Member of the Audit Committee.

Each director elected or appointed will hold office until the next annual general meeting of Entheon or until his or her successor is elected or appointed, unless his or her office is earlier vacated in accordance with the By-laws of Entheon or with the provisions of the CBCA.

## 13.2 Board Committees

### Audit Committee

The members of Entheon's Audit Committee are:

|                               |                                |                                     |
|-------------------------------|--------------------------------|-------------------------------------|
| Dr. Christopher Gondi (Chair) | Independent <sup>(1)</sup>     | Financially literate <sup>(2)</sup> |
| Timothy Ko                    | Not Independent <sup>(1)</sup> | Financially literate <sup>(2)</sup> |
| Ruth Chun                     | Independent <sup>(1)</sup>     | Financially literate <sup>(2)</sup> |

- (1) A member of an audit committee is independent if the member has no direct or indirect material relationship with Entheon, which could, in the view of the Entheon Board, reasonably interfere with the exercise of a member's independent judgment.
- (2) An individual is financially literate if he/she has the ability to read and understand a set of financial statements that present a breadth of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by Entheon's financial statements.

The Entheon Board will adopt a written charter setting forth the responsibilities, powers and operations of the Audit Committee consistent with NI 52-110. The duties and responsibilities of the Audit Committee include those related to:

- (a) the integrity of Entheon's consolidated financial statements and accounting and financial processes and the audits of our consolidated financial statements;
- (b) Entheon's compliance with legal and regulatory requirements;
- (c) Entheon's external auditors' qualifications and independence;
- (d) the work and performance of Entheon's financial management and its external auditors; and
- (e) Entheon's system of disclosure controls and procedures and system of internal controls regarding finance, accounting, legal compliance, and risk management established by management and the Entheon Board.

The Audit Committee has access to all books, records, facilities and personnel and may request any information about Entheon as it may deem appropriate. It has the authority to retain and compensate special legal, accounting, financial and other consultants or advisors to advise the Audit Committee. The Audit Committee is also expected to review and approve all related-party transactions and prepare reports for the Entheon Board on such related-party transactions as well as be responsible for the pre-approval of all non-audit services to be provided by Entheon's auditors.

Entheon is a "venture issuer", as defined in National Instrument 52-110 – *Audit Committees*. As such, Entheon is relying on the exemption contained in section 6.1 of National Instrument 52-110 – *Audit Committees*, which exempts Entheon from the requirements of Part 3 (Composition of the Audit Committee) and Part 5 (Reporting Obligations).

There is no intention to create another committee of the Entheon Board at this time.

### **13.3 Officer of Other Companies**

None of the directors or officers of Entheon, act, in their principal occupation, as an officer of a person or company other than Entheon.

### **13.4 Penalties, Sanctions and Bankruptcy**

To the knowledge of Entheon, no director, officer, promoter or shareholder who holds a sufficient number of Entheon's securities to affect materially control of Entheon is, or has been within 10 years before the date of this Listing Statement, a director or officer of any other issuer that, while that person was acting in that capacity:

- (a) was the subject of a cease trade order or similar order or an order that denied that issuer access to any exemptions under Ontario securities law, for a period of more than 30 consecutive days;
- (b) was subject to an event that resulted, after the director or executive officer ceased to be a director or executive officer, in the company being the subject of a cease trade or similar order or an order that

denied the relevant company access to any exemption under securities legislation, for a period of more than 30 consecutive days;

- (c) 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
- (d) 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.

To the knowledge of Entheon, none of Entheon's directors or officers, nor a shareholder holding a sufficient number of Entheon's securities to affect materially control of Entheon, has:

- (a) been subject to any penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities regulatory authority or has entered into a settlement agreement with a Canadian securities regulatory authority; or
- (b) been subject to any other penalties or sanctions imposed by a court or regulatory body that would be likely to be considered important to a reasonable investor making an investment decision.

To the knowledge of Entheon, none of Entheon's directors or officers, nor a shareholder holding a sufficient number of Entheon's securities to affect materially control of Entheon, or a personal holding company of any such persons has, within the 10 years before the date of this Listing Statement, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or been subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold their assets.

### **13.5 Existing or Potential 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 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.

### **13.6 Management**

The following is a brief description of each member of management of Entheon.

#### ***Timothy Ko, age 35, Chief Executive Officer, President and Director***

As a Director, Chief Executive Officer and President of Entheon, Mr. Ko's responsibilities include:

- providing input into and ensuring compliance with corporate goals and objectives developed or approved by the Entheon Board;

- managing Entheon's general corporate matters and providing strategic planning advice with respect to the growth and development of the business and operations of Entheon;
- engaging, hiring, overseeing and terminating of employees, consultants and advisors, except as otherwise provided by the Entheon Board, and more particularly to: (i) hire, retain, oversee and terminate corporate officers, employees, consultants and advisors; and (ii) define the scope of work and responsibilities or services to be provided by such persons;
- in coordination with appropriate committees of the Entheon Board, initiating and reviewing proposals on such matters as (i) corporate governance or management practices and reporting; (ii) financing and investment; (iii) acquisitions and restructuring; (iv) new business opportunities; and (v) major capital and operational expenditures;
- communicating with Entheon's professional advisors including, without limitation, its solicitors, auditors, financial agents and independent consultants with respect to the operations, business, assets and activities of Entheon and its subsidiaries;
- developing annual business plans and budgets while ensuring consistency with the strategic plans, policies and other strategic directions of Entheon;
- overseeing Entheon's business conduct and ensuring that such conduct is consistent with the values of Entheon, including (i) overseeing corporate communications, both internal and external; and (ii) ensuring the integrity and orderly conduct of Entheon and its workplaces;
- overseeing legal compliance and risk management, including (i) developing and implementing systems to ensure that material risks and obligations are identified and assessed; (ii) taking appropriate steps to ensure oversight of employees, consultants and agents of Entheon; and (iii) leading programs for and development of policies in respect of risk management; and
- such other duties as may be specified by the Entheon Board, from time to time.

Mr. Ko's passion for the Entheon space is shaped by firsthand knowledge of the shortcomings of the current mental health system and through his exposure to psychedelics which he credits with saving his life. Following the loss of a loved one to a decades' long fight with mental health and addictions, and through his personal experiences, Mr. Ko was delighted to commit himself to the lifesaving potential of this new frontier of medicine. Mr. Ko attended a variety of universities with a broad range of studies covering finance, literature, sociology, and psychology. Mr. Ko is an employee of Entheon and expects to devote 100% of his time to the affairs of Entheon. Mr. Ko has executed a management agreement, which among other things, contains non-disclosure provisions, non-competition and non-solicitation provisions, the latter two of which apply during the course of employment and within twelve (12) months following the termination of employment.

Mr. 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. To the knowledge of Mr. Ko., Hyperbridge Technology is still carrying on business. Previous to that Mr. Ko served as President of Acom Building Maintenance. To the knowledge of Mr. Ko, Acom Building Maintenance which operates in the commercial building services sector is still carrying on business.

***Brandon Schwabe, CPA, CGA, age 34, Chief Financial Officer***

As Chief Financial Officer of Entheon, Mr. Schwabe works closely with the senior management of Entheon to assist in the development and support of strategic plans, budgets, cash management, financial reporting, and compliance. Mr. Schwabe is a Chartered Professional Accountant (CPA, CGA) who qualified in 2016. He also holds a

Bachelor of Technology in Accounting degree with distinction from the British Columbia Institute of Technology and has completed the Canadian Securities Course (CSC) from the Canadian Securities Institute.

Mr. Schwabe is an employee of Entheon and expects to devote 100% of his time to the affairs of Entheon. Mr. Schwabe has executed a management agreement, which among other things, contains non-disclosure provisions, non-competition and non-solicitation provisions, the latter two of which apply during the course of employment and within twelve (12) months following the termination of employment.

Mr. Schwabe, CPA, CGA has extensive professional experience in finance and accounting. He draws from over a decade working with private enterprises across the real estate and construction sector. Most recently from October 2017 to April 2019, Mr. Schwabe worked as the Controller for Unison Construction Management, a design build construction management company. Prior to that from September 2013 to June 2017, Mr. Schwabe worked as a Project Accountant for Kasian Architecture, an architecture, interior design and planning firm.

***Dr. Andrew Hegle, Ph.D. age 42, Chief Science Officer and Director***

As a Director and the Chief Science Officer of Entheon, Dr. Hegle oversees the scientific research and development of Entheon by establishing and maintaining relationships, timelines and budgets of significant research. He received his Ph.D. in Molecular, Cellular and Developmental Biology from the University of Michigan in 2007. Dr. Hegle is an employee of Entheon and expects to devote 100% of his time to the affairs of Entheon. Dr. Hegle has executed a management agreement, which among other things, contains non-disclosure provisions, non-competition and non-solicitation provisions, the latter two of which apply during the course of employment and within twelve (12) months following the termination of employment.

Dr. Hegle has been an adjunct professor of Pharmacology at the University of British Columbia since 2015. He has a background in molecular biology and biochemistry and has published research investigating the role of membrane receptor proteins in physiology, behavior and disorder. Dr. Hegle's main professional focus has been in the creation and management of laboratory operations. To that end, Dr. Hegle has held executive and operational management positions at several biotechnology companies, and was a cofounder of Cannevert Therapeutics Ltd., a company that provides medical products, conducts Cannabis research and performs chemical Cannabis laboratory testing for the country's various cannabis programs. Dr. Hegle served as Senior Scientist from December 2015 to June 2018 and Director of Regulatory Affairs and Quality Assurance from July 2018 to January 2020. Dr. Hegle has a long-held interest in the therapeutic potential of psychedelic medicine and is delighted to commit himself to furthering this field.

***Dr. Christopher Gondi, Ph.D., M.Sc. age 49, Director and Science Advisor***

As a director and Science Advisor of Entheon, Dr. Gondi provides general oversight and scientific opinion on the business of Entheon. Dr. Gondi has a BSc in Life Sciences, and a MSc in Botany with a specialization in Microbiology from Joseph's College Bangalore, Bangalore University India. He also has a Ph.D. in Genetics from Osmania University Hyderabad India.

Dr. Gondi is an independent contractor of Entheon. Dr. Gondi expects to devote 50% of his time to the affairs of Entheon. Dr. Gondi has entered into a consulting agreement with Entheon containing both non-disclosure provisions and non-solicitation provisions, the latter of which apply during the course of engagement and within two years months following the termination of the consulting agreement.

Dr. Gondi's principal occupation is and has been for the past five years a Research Assistant Professor in the Department of Medicine, Surgery and Pathology at the University of Illinois College of Medicine Peoria. Dr. Gondi 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. Knowing firsthand the difficulty many face as they approach the end of their lives, Dr. Gondi seeks to explore the therapeutic benefits of psychedelic drugs in

helping patients reconcile their views and prepare for whatever exists beyond life. He also sees the transformative potential of these drugs in positively affecting the lives of those suffering from substance use disorders.

***Kelly Pladson age 38, Corporate Secretary***

As the Corporate Secretary of Entheon, Ms. Pladson works closely with Entheon's officers, directors and legal counsel in maintaining corporate records and ensuring Entheon's filings with the securities commissions and exchanges are accurately filed and in accordance with their deadlines.

Ms. Pladson is an independent contractor of Entheon and expects to devote 20% of her time to the affairs of Entheon. Ms. Pladson has entered into a consulting agreement with Entheon containing both non-disclosure provisions and non-solicitation provisions, the latter of which apply during the course of engagement and within twelve (12) months following the termination of the consulting agreement.

Ms. Pladson has provided corporate governance and regulatory compliance services to many TSX Venture Exchange and Canadian Securities Exchange listed companies since 2009. She is currently or was previously the Corporate Secretary of the following mining and exploration issuers listed on the TSXV Venture Exchange: Gaia Metals Corp. (2017 to present), Aben Resources Ltd. (2017 to present), Cypress Development Corp. (2017 to present), Le Mare Gold Corp. (2019 to present), Max Resource Corp. (2018 to present), Megastar Development Corp. (2018 to present), Resolve Ventures Inc. (2017 to 2019), Rockridge Resources Ltd. (2019 to present) and Skyharbour Resources Ltd. (2017 to present). In addition, she currently is or was previously the Corporate Secretary for the following other TSX Venture Exchange listed companies: RevoluGroup Canada Inc., a technology company (2017 to 2019) and Tri Capital Opportunities Corp., a capital pool company (2019 to present). Additionally, she is currently or was previously the Corporate Secretary for the following issuers listed on the Canadian Securities Exchange: Alchemist Mining Inc., a mining company (2017 to 2019), ImagineAR Inc., a technology company (2017 to 2018), Bam Resources Corp., a mining and exploration company (2018 to present), Nova Mentis Life Science Corp., a life sciences company (2017 to present) and Lightning Ventures Inc., an oil and gas technology company (2017 to 2018).

***Ruth Chun age 41, Director***

As a director of Entheon, Ms. Chun acts as an independent director and member of the Audit Committee. Ms. Chun is an independent contractor of Entheon and expects to devote 20% of her time to the affairs of Entheon. Ms. Chun has not entered into a non-competition or non-disclosure agreement with Entheon. Ms. Chun has Honours Bachelor of Arts from University of Toronto (Trinity College), Master of Arts (University of Toronto) and Juris Doctor (Queen's University). Ms. Chun 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, 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. Ms. Chun is a regularly sought-after speaker for her expertise in the cannabis and psychedelics industries. She is a guest lecturer at several universities on cannabis law and is a lecturer and has served on the Advisory Board for the Osgoode Certificate in Cannabis Law & Regulations since February 2020. 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 Rossing Pension Fund, Rio Tinto's defined benefits fund from March 2016 to August 2017.

## 14. CAPITALIZATION

### 14.1 Issued Capital

The following tables provide information about the capitalization of Enttheon's Common Shares as of the date of this Listing Statement:

| Issued Capital <sup>(1)</sup>                                                                                                                                                                                                                                                                                                                                                                  | Number of Securities (non-diluted) | Number of Securities (fully-diluted) | % of Issued (non-diluted) | % of Issued (fully diluted) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------------------------|---------------------------|-----------------------------|
| <b>Public Float</b>                                                                                                                                                                                                                                                                                                                                                                            |                                    |                                      |                           |                             |
| <b>Total Outstanding (A)</b>                                                                                                                                                                                                                                                                                                                                                                   | <b>40,388,851</b>                  | <b>51,830,618</b>                    | <b>100%</b>               | <b>100%</b>                 |
| Held by Related Persons or employees of the Enttheon or Related Person of the Enttheon, or by persons or companies who beneficially own or control, directly or indirectly, more than a 5% voting position in Enttheon (or who would beneficially own or control, directly or indirectly, more than a 5% voting position in Enttheon upon exercise or conversion of other securities held) (B) | 11,850,001                         | 11,650,001                           | 29.34%                    | 22.48%                      |
| <b>Total Public Float (A-B)</b>                                                                                                                                                                                                                                                                                                                                                                | <b>28,538,850 <sup>(2)</sup></b>   | <b>38,880,617</b>                    | <b>70.66%</b>             | <b>75.01%</b>               |
| <b>Freely-Tradeable Float</b>                                                                                                                                                                                                                                                                                                                                                                  |                                    |                                      |                           |                             |
| Number of outstanding securities subject to resale restrictions, including restrictions imposed by pooling or other arrangements or in shareholder agreement and securities held by control block holders (C)                                                                                                                                                                                  | 3,126,418                          | 3,126,418                            | 7.74%                     | 6.03%                       |
| <b>Total Tradeable Float (A-C)</b>                                                                                                                                                                                                                                                                                                                                                             | <b>37,262,433</b>                  | <b>48,704,200</b>                    | <b>92.26%</b>             | <b>93.97%</b>               |

<sup>(1)</sup> Figures are reported to the best of the knowledge of management of Enttheon and on a post-Consolidated basis.

<sup>(2)</sup> All of these 28,538,850 Common Shares are freely tradeable and are held by 303 public shareholders of Enttheon that hold a board lot, being 500 Common Shares, under this figure.

### Public Securityholders (Registered)

The following table sets forth information regarding the number of registered "public securityholders" of Enttheon, being persons other than persons enumerated in section (B) of the *Issued Capital* table above:

### Class of Security: Common Shares

| Size of Holding          | Number of Holders | Total Number of Securities <sup>(1)</sup> |
|--------------------------|-------------------|-------------------------------------------|
| 1 – 99 securities        | Nil               | Nil                                       |
| 100 – 499 securities     | Nil               | Nil                                       |
| 500 – 999 securities     | Nil               | Nil                                       |
| 1,000 – 1,999 securities | Nil               | Nil                                       |
| 2,000 – 2,999 securities | Nil               | Nil                                       |
| 3,000 – 3,999 securities | Nil               | Nil                                       |
| 4,000 – 4,999 securities | Nil               | Nil                                       |
| 5,000 or more securities | 128               | 28,718,861                                |
| Unable to confirm        | N/A               | N/A                                       |

|               |            |                   |
|---------------|------------|-------------------|
|               |            |                   |
| <b>TOTAL:</b> | <b>128</b> | <b>28,718,861</b> |

<sup>(1)</sup> Figures are reported to the best of the knowledge of management of Entheon and on a post-Consolidated basis.

### Public Securityholders (Beneficial)

The following table sets forth information regarding the number of beneficial “public securityholders” of Entheon, being persons other than persons enumerated in section (B) of the *Issued Capital* table above who either: (i) hold securities in their own name as registered shareholders; or (ii) hold securities through an intermediary where Entheon has been given written confirmation of shareholdings:

#### *Class of Security: Common Shares*

| Size of Holding          | Number of Holders                                                                | Total Number of Securities <sup>(1)</sup>                                        |
|--------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1 – 99 securities        | Nil                                                                              | Nil                                                                              |
| 100 – 499 securities     | 5                                                                                | 1,591                                                                            |
| 500 – 999 securities     | 62                                                                               | 51,244                                                                           |
| 1,000 – 1,999 securities | 12                                                                               | 18,944                                                                           |
| 2,000 – 2,999 securities | 2                                                                                | 4,666                                                                            |
| 3,000 – 3,999 securities | 36                                                                               | 93,161                                                                           |
| 4,000 – 4,999 securities | 53                                                                               | 247,732                                                                          |
| 5,000 or more securities | 217                                                                              | 18,758,628                                                                       |
| Unable to confirm        | Cannot accurately confirm the shareholdings of objecting beneficial shareholders | Cannot accurately confirm the shareholdings of objecting beneficial shareholders |
| <b>TOTAL:</b>            | <b>387</b>                                                                       | <b>19,176,016</b>                                                                |

<sup>(1)</sup> Figures are reported to the best of the knowledge of management of Entheon and on a post-Consolidated basis.

### Non-Public Securityholders (Registered)

The following table sets forth information regarding the number of registered “non-public securityholders” of Entheon, being persons enumerated in section (B) of the issued capital chart:

#### *Class of Security: Common Shares*

| Size of Holding          | Number of Holders | Total Number of Securities <sup>(1)</sup> |
|--------------------------|-------------------|-------------------------------------------|
| 1 – 99 securities        | Nil               | Nil                                       |
| 100 – 499 securities     | Nil               | Nil                                       |
| 500 – 999 securities     | Nil               | Nil                                       |
| 1,000 – 1,999 securities | Nil               | Nil                                       |
| 2,000 – 2,999 securities | Nil               | Nil                                       |
| 3,000 – 3,999 securities | Nil               | Nil                                       |
| 4,000 – 4,999 securities | Nil               | Nil                                       |
| 5,000 or more securities | 7                 | 11,850,001                                |
| Unable to confirm        | N/A               | N/A                                       |
| <b>TOTAL:</b>            | <b>7</b>          | <b>11,850,001</b>                         |

<sup>(1)</sup> Figures are reported to the best of the knowledge of management of Entheon and on a post-Consolidated basis.

## 14.2 Convertible Securities

The following table summarizes the outstanding securities convertible into Common Shares as of the date of this Listing Statement:

| Description of Security (include conversion/exercise terms, including conversion/exercise price) | Number of convertible/exchangeable securities outstanding | Number of listed securities issuable upon conversion/exercise | Exercise Price | Expiry Dates      |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------|----------------|-------------------|
| Warrants                                                                                         | 651,143                                                   | 651,143                                                       | \$0.75         | December 4, 2020  |
| Warrants                                                                                         | 13,334                                                    | 13,334                                                        | \$0.45         | December 4, 2020  |
| Warrants                                                                                         | 1,988,500                                                 | 1,988,500                                                     | \$0.90         | April 20, 2021    |
| Warrants                                                                                         | 2,000,000                                                 | 2,000,000                                                     | \$0.48         | February 12, 2021 |
| Warrants                                                                                         | 35,000                                                    | 35,000                                                        | \$0.50         | December 18, 2021 |
| Warrants                                                                                         | 1,020,000                                                 | 1,020,000                                                     | \$0.50         | December 23, 2021 |
| Warrants                                                                                         | 687,500                                                   | 687,500                                                       | \$0.50         | January 30, 2022  |
| Warrants                                                                                         | 2,620,402                                                 | 2,620,402                                                     | \$0.60         | June 3, 2022      |
| Warrants                                                                                         | 2,108,943                                                 | 2,108,943                                                     | \$0.60         | November 5, 2022  |
| Replacement Broker Warrants <sup>(1)</sup>                                                       | 211,297                                                   | 316,945                                                       | \$0.375        | September 3, 2022 |

<sup>(1)</sup> Exercisable into Replacement Broker Warrant Units at an exercise price of \$0.375 for a period of two years from the closing of the Subco Private Placement, with each Broker Warrant Unit being comprised of one Common Share and one-half of one Underlying Replacement Broker Warrant.

## 14.3 Other Listed Securities

Entheon has no other listed securities reserved for issuance that are not included in the section above.

## 15. EXECUTIVE COMPENSATION

For the purposes of this section, the Named Executive Officers (or “NEOs”) are the Chief Executive Officer and Chief Financial Officer of Entheon and the most highly compensated executive officer who is proposed to serve as an executive officer of Entheon for the 12 month period following the completion of the Transaction and whose total compensation, individually, will be more than \$150,000. Based on the above criteria, the only NEOs for Entheon are Timothy Ko (President and Chief Executive Officer), Brandon Schwabe (Chief Financial Officer) and Andrew Hagle (Chief Science Officer). There are no other NEOs of Entheon other than the Chief Executive Officer, Chief Financial Officer and Chief Science Officer, as no other executive officers will be paid compensation exceeding \$150,000 for the 12-month period following the Transaction.

### 15.1 Oversight and Description of Director and Named Executive Officer Compensation

#### Compensation of NEOs and Directors

The Entheon Board has developed appropriate compensation policies for both the officers and the directors of Entheon. In determining appropriate compensation levels, the Entheon Board has reviewed compensation paid for directors and officers of companies of similar size and stage of development in the research and development industry and has determined appropriate compensation policies that reflect the need to provide incentive and compensation for the time and effort expended by the directors and senior management while taking into account the financial and other resources of Entheon.

Entheon relies solely on the Entheon Board to determine, by way of discussions at Entheon Board meetings, semi-annually, the executive compensation that is to be paid to NEOs and directors without any formal objectives, criteria, or analysis.

The general objectives of Entheon's compensation strategy are to: (a) compensate management in a manner that encourages and rewards a high level of performance and outstanding results with a view to increasing long term shareholder value; (b) align management's interests with the long term interests of shareholders; (c) provide a compensation package that is commensurate with other companies to enable Entheon to attract and retain talent; and (d) ensure that the total compensation package is designed in a manner that takes into account the constraints that Entheon is under by virtue of the fact that it is a start-up company without a history of earnings.

In the most recently completed financial year, no compensation was directly tied to a specific performance goal such as a milestone or the completion of a transaction, no significant events occurred that significantly affected compensation, and no peer group was formally used to determine compensation – Entheon does not expect this to change in the upcoming financial year.

### Elements of Compensation for NEOs

The significant elements of compensation awarded to, earned by, paid or payable to the NEOs for the most recently completed financial year were: (i) base salary; and (ii) incentive awards in the form of Options. Entheon anticipates that these will also be the significant elements of compensation for NEOs in the upcoming financial year. The amount to be paid for each element of compensation is not based on any formula or specific objective criteria but is the result of a subjective determination of the Entheon's Board in consideration of a number of factors, including, but not limited to: the overall financial and operating performance of Entheon, each NEO's individual performance and contribution towards meeting corporate objectives, each NEO's level of responsibility, each NEO's length of service, industry comparables and Entheon's ability to pay compensation.

### 15.2 Director and NEO Compensation Excluding Compensation Securities

In the following 12-month period, Entheon anticipates compensating the NEOs as follows (in each case, pursuant to the Management Agreements):

| TABLE OF COMPENSATION EXCLUDING COMPENSATION SECURITIES  |                                                     |            |                                |                           |                                      |                         |
|----------------------------------------------------------|-----------------------------------------------------|------------|--------------------------------|---------------------------|--------------------------------------|-------------------------|
| Name and Position <sup>(2)</sup>                         | Salary, Consulting Fee, Retainer or Commission (\$) | Bonus (\$) | Committee or Meeting Fees (\$) | Value of Perquisites (\$) | Value of all Other Compensation (\$) | Total Compensation (\$) |
| Timothy Ko, President, Chief Executive Officer, Director | 130,000                                             | Nil        | Nil                            | Nil                       | Nil                                  | 130,000                 |
| Brandon Schwabe, CPA, CGA, Chief Financial Officer       | 110,000                                             | Nil        | Nil                            | Nil                       | Nil                                  | 110,000                 |
| Andrew Hegle, Chief Science Officer, Director            | 120,000                                             | Nil        | Nil                            | Nil                       | Nil                                  | 120,000                 |

Directors who are not executive officers are expected to receive compensation in the following 12-month period in an amount to be negotiated.

### 15.3 Stock Options and Other Compensation Securities

As of the date hereof, there are no Options outstanding:

Entheon intends to use stock option grants in the future to align executive interests with those of shareholders and such option grants will be based on the executive's performance, level of responsibility, as well as the number and exercise price of options previously issued to the executive pursuant to such executive's overall aggregate total compensation package.

#### **15.4 Stock Option Plan**

Pursuant to the Stock Option Plan, Entheon may grant Options up to a maximum of 10% of Entheon's issued and outstanding share capital at the time of grant.

##### **Material Terms of the Stock Option Plan**

Pursuant to the Stock Option Plan, Entheon may, at its discretion, grant to directors, officers, employees or consultants of Entheon options to acquire Common 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 Stock Option Plan the total number of securities reserved for issuance will be equivalent to 10% of the number of Common Shares issued and outstanding at any given time. The Stock Option Plan is administered by the Entheon Board, which has full authority to grant all the options associated with it. Options may be granted under the Stock Option Plan to the Service Providers of Entheon and its subsidiaries, if any, that the Entheon Board may designate from time to time. The exercise price will be set by the Entheon 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 Stock Option Plan provides that the number of Common 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 Common Shares issued and outstanding, on an undiluted basis, at any given time. In addition, the number of Common 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 Common 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 Stock Option Plan expire on the date set by the Entheon Board as the option expiry date, which must not be later than five years from the option grant date. Options granted under the Stock 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.

#### **15.5 Employment, Consulting and Management Agreements**

Each of Timothy Ko, Andrew Hagle and Brandon Schwabe (each an "**Employee**") have executed Management Agreements, the material terms of which are set forth below:

- **Salary:** Timothy Ko's annual salary is \$130,000; Andrew Hagle's annual salary is \$120,000; and Brandon Schwabe's annual salary is \$110,000.
- **Bonus and Options:** Entheon may, in its sole discretion, grant a bonus or Options to the Employee in any amount deemed reasonable and appropriate by the Entheon's Board based on the Employee's performance, Entheon's performance and any other relevant factors determined in Entheon's sole discretion.
- **Vacation:** The Employee is entitled to four (4) weeks of paid vacation.

- **Resignation:** The Employee may resign by providing Entheon with 30 days' prior written notice. Entheon may waive such notice in which case the Employee's resignation will become effective on the day elected by Entheon and Entheon will pay the Employee the lesser of: (i) compensation in lieu of the notice that would have been applicable if Entheon had terminated the Employee's employment without just cause; and (ii) compensation in lieu of the period of notice provided by the Employee that has been waived by Entheon.
- **Termination for Cause:** The Employee's employment may be terminated by Entheon for just cause as defined at common law, by providing the Employee with notification in writing, and the Employee will not be entitled to any notice or compensation in lieu of notice.
- **Termination without Cause:** Entheon may terminate the Employee's employment at any time without cause by: (i) providing the Employee with three (3) months' notice in writing plus two additional weeks' notice for each completed year of service up to a maximum of eight (8) months' notice (the "**Working Notice**"); or (ii) at the sole discretion of Entheon, it may choose to pay to the Employee, in lieu of all or part of the Working Notice, an amount equal to that portion of the Employee's Salary that the Employee would have earned during all or the remaining portion of the Working Notice period, less all statutory deductions.
- **Change of Control:** If within six (6) months following a change of control of Entheon, Entheon terminates the Employee's employment without just cause, Entheon will: (i) pay the Employee pay in lieu of notice pursuant to section 11(c) of the Management Agreement, either through continuing salary, or, in Entheon's sole discretion, as a lump sum (the "**Severance Payment**"); and (ii) in addition to the Severance Payment, pay the Employee six (6) months' Salary less statutory deductions, either through continuing salary, or, in Entheon's sole discretion, as a lump sum.
- **Non-Competition and Non-Solicitation:** The Employee is subject to 12-month non-solicitation and non-competition restrictions which apply during the course of employment and within twelve (12) months following the termination of employment.

Please see information under the heading "*Specialized Skill and Knowledge*" for a summary of the material terms of the consultant agreements entered into by Entheon and its Science Advisors.

## 15.6 Pension Disclosure

Entheon does not anticipate having a pension plan that provides for payments or benefits to the NEOs or directors at, following, or in connection with retirement.

## 15.7 Compensation of Directors

Entheon relies solely on the Entheon Board to determine, by way of discussions at Entheon Board meetings, the compensation that is to be paid to directors without any formal objectives, criteria, or analysis. Entheon expects to pay compensation by way of quarterly cash payment fees to certain of its directors for services as a director. Directors will also be eligible to receive Option grants under the Stock Option Plan.

## 16. INDEBTEDNESS OF DIRECTORS AND EXECUTIVE OFFICERS

No director or officer of Entheon, no other individual who at any time during the most recently completed financial year was a director or executive officer of Entheon, nor any associate of the such individuals is, or at any time since the beginning of the most recently completed financial year of Entheon has been, indebted to:

- (a) Entheon or any of its subsidiaries; or
- (b) another entity, which indebtedness is or was the subject of a guarantee, support

agreement, letter of credit or other similar transaction or understanding provided by Entheon or any of its subsidiaries.

## **17. RISK FACTORS**

Entheon's securities are highly speculative due to the nature of Entheon's business and an investment in Entheon's securities should only be made by investors who can afford to lose their entire investment. An investment in Entheon's securities is highly speculative, not only due to the nature of Entheon's business and operations, but also because of the uncertainty related to the recent integration of the business of Entheon Holdings into Entheon pursuant to the Amalgamation. Before making an investment decision, in addition to the other information in this Listing Statement (including all Schedules hereto), an investor should carefully consider each of, and the cumulative effect of, the following risk factors.

### **17.1 Risk Relating to the Common 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 established or 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 Common Shares, existing holders of such Common Shares may experience dilution in their holdings. Moreover, when Entheon's intention to issue additional equity securities becomes publicly known, the price of the Common Shares may be adversely affected.

#### **Dividends**

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

### **17.2 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 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 psychedelic therapeutic solution portfolio through clinical development, advancing the remainder of the existing portfolio through preclinical studies and into IND's or their equivalent, and sponsoring research with its development partners. Developing pharmaceutical solutions, including conducting preclinical studies both invitro and invivo 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 updated 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 Solutions;
- 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 Solutions;
- the costs of acquiring, licensing or investing in businesses, products, psychedelic therapeutic solutions and technologies;
- 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 solutions;
- its need to implement additional internal systems and infrastructure, including financial and reporting systems;
- research grant terms that change over time or whose terms Entheon is unable to meet;
- grants that Entheon relied upon are not funded for any reason;
- 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 Solutions 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 Common Shares, or the possibility of such issuance, may cause the market price of the Common 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 solutions 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, and establishing key relationships. Entheon has yet to commence clinical trials for the psychedelic therapeutic solutions 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 an 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 no products approved for commercial sale, and to date it has not generated any 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. Entheon has not yet submitted any psychedelic therapeutic solutions for approval by regulatory authorities in Canada, the European Union, the United States or elsewhere. For the year ended November 30, 2019, Entheon's subsidiary, Entheon Holdings, incurred a net loss of \$278,028. For the nine months ended August 31, 2020, Entheon Holdings incurred a net loss of \$1,061,062.

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 Solutions, 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 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 Solutions 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 "*Narrative Description of the Business – Regulatory Regimes*" 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. 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 "*Expected Changes*" 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 Solutions, or if, subsequent to approval, 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 Solutions**

Delays in the commencement, enrolment and completion of preclinical and clinical trials could increase Entheon's solution development costs or limit the regulatory approval of its DMT Solutions. Entheon does not know whether any future trials or studies of its other psychedelic therapeutic solutions 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 solutions 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 solutions, 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 solutions 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 FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

**Entheon has no 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 no 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 solutions 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 solutions, 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.

**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 solutions 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 3 full-time employees and 16 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.

**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 Common 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 Entheon 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 Entheon 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 Common 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 Listing Statement.

## **Impact of COVID-19**

Entheon's business, operations and financial condition could be materially and adversely affected by the outbreak of epidemics or pandemics or other health crises, including the recent outbreak of COVID-19. On January 30, 2020, the World Health Organization declared the outbreak of a global health emergency and on March 13, 2020 the U.S. 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.

## **17.3 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 Common 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.

## **17.4 Risks Relating to the Psychedelic Therapy Market and Pharmaceutical Industry**

### **The psychedelic therapy industry and market 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 solution 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 solutions 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 solutions obsolete, less competitive or not economical.

#### **Changes in 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**

Psychedelic therapy is a new and emerging industry with ambiguous existing regulations and uncertainty as to future regulations. Certain psychedelics may be illegal substances other than when used for scientific or medical purposes. As such, new risks may emerge, and management may not be able to predict all such risks or be able to predict how such risks may result in actual results differing from the results contained in any forward-looking

statements. This industry is subject to extensive controls and regulations, which may significantly affect the financial condition of market participants. The marketability of any product may be affected by numerous factors that are beyond the control of v and cannot be predicted, such as changes to government regulations, including those relating to taxes and other government levies which may be imposed. Changes in government levies, including taxes, could reduce Entheon's earnings and could make future capital investments or operations uneconomic. The psychedelic therapy industry is also subject to numerous legal challenges, which may significantly affect the financial condition of market participants and which cannot be reliably predicted.

## **17.5 Regulatory Risks and Risks Related to Local and Foreign Operations**

### **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 and DMT Delivery System, 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 and DMT Delivery System. 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.

### **Risks associated with delays in clinical testing**

Entheon cannot predict whether any clinical trials will commence as planned, will need to be restructured, or will

be completed on schedule, or at all. Although Entheon does not anticipate delays specifically related to the foreign jurisdiction of clinical trial(s), any delays could shorten the period during which the company may have the exclusive right to commercialize its products, or could provide room for competitors to bring products to market. The commencement and completion of clinical trials may be delayed for a number of reasons, including delays related but not limited to:

- regulatory authorities' failure to grant permission to proceed or placing the clinical trial on hold;
- patients failing to enroll or remain in Entheon's trials at the rate Entheon expects;
- suspension or termination of clinical trials by regulators for a variety of reasons, including failure of CHDR or other contract research organizations to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities, regulatory authorities or ethics committees finding regulatory violations that require Entheon to undertake corrective action;
- one or more regulatory authorities or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial;
- product candidates demonstrating a lack of safety or efficacy during clinical trials;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- reports of clinical testing on similar technologies and products raising safety or efficacy concerns;
- competing clinical trials and scheduling conflicts with participating clinicians;
- clinical investigators not performing Entheon's clinical trials within their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner; and
- the impact of COVID-19 on the personnel, business, operations, or financial condition on Entheon, its research partners or its suppliers.

#### **Regulatory approval risk**

Entheon's development and commercialization activities and product candidates are and will be significantly regulated by a number of governmental entities, including Health Canada, the EMA, and the FDA. Regulatory approvals are required prior to each clinical trial and Entheon may fail to obtain the necessary approvals to commence or continue clinical testing in one or more jurisdictions. The time required to obtain approval by regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials. Any analysis of data from clinical activities Entheon performs is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary by jurisdiction.

Entheon could fail to receive regulatory approval for Entheon's product candidates 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.

#### **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 "*Narrative Description of the Business – Overview*" 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 its intellectual property from unauthorized use by third parties only to the extent that 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.

## **18. 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 Common Shares representing 3.22% of the issued and outstanding Common Shares as of the date of this Listing Statement. 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 Listing Statement 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 Officers*" and "*Executive Compensation*."

## **19. LEGAL PROCEEDINGS**

Neither Entheon, nor its subsidiary, are party to, nor is any of their respective property the subject matter of, any legal proceeding or to the knowledge of Entheon any contemplated legal proceeding, which in any such case is material to Entheon. From time to time, however, Entheon or any of its subsidiaries may be subject to various claims and legal actions arising in the ordinary course of business.

Entheon has not been subject to any penalties or sanctions imposed by a court relating to provincial and territorial securities legislation or a securities regulatory authority, any other penalties or sanctions imposed by a court or regulatory body, nor any settlement agreements entered into before a court relating to provincial and territorial securities legislation or with a securities regulatory authority within the three years immediately preceding the date hereof.

## **20. INTEREST 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 Listing Statement, or in any proposed transaction, that has materially affected or will materially affect Entheon.

## **21. AUDITORS, TRANSFER AGENTS AND REGISTRARS**

### **21.1 Auditor**

The auditor of Entheon is Manning Elliott LLP, Chartered Professional Accountants, of 1030 West Georgia St #1700, Vancouver, BC V6E 2Y3.

### **21.2 Transfer Agent and Registrar**

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

## **22. MATERIAL CONTRACTS**

Except for contracts entered into in the ordinary course of business, the only contracts entered into by Entheon in the two years immediately prior to the date hereof that can reasonably be regarded as material to Entheon are as follows:

- (a) the Amalgamation Agreement;
- (b) the CHDR Clinical Study Agreement, as discussed in further detail above under the headings “*General Development of the Business – History – Contracts and “Narrative Description of the Business – Research and Development Studies – Timing, Cost, Stage of Development & Major Components of Proposed Studies”*”; and
- (c) the Psygen Supply Agreement, as discussed in further detail above under the headings “*General Development of the Business – History – Contracts and “Narrative Description of the Business – Research and Development Studies – Timing, Cost, Stage of Development & Major Components of Proposed Studies”*”.

## **23. INTEREST OF EXPERTS**

To the best of Entheon’s knowledge, no person or company whose profession or business gives authority to a statement made by the person or company and who is named as having prepared or certified a part of this Listing Statement or who prepared or certified a report or valuation described or included in this Listing Statement: (i) has received or will receive any direct or indirect interests in the property of Entheon or of a Related Person (as defined in the policies of the CSE) of Entheon; or (ii) has any beneficial ownership, direct or indirect of any securities of Entheon or any Related Person (as defined in the policies of the CSE) of Entheon.

## **24. OTHER MATERIAL FACTS**

There are no material facts about Entheon and its securities that are not disclosed under the preceding items and are necessary in order for this Listing Statement to contain full, true and plain disclosure of all material facts relating to Entheon and its securities

## **25. FINANCIAL STATEMENTS**

The following financial statements and related MD&A are attached as schedules to this Listing Statement.

Schedule “A” - Financial Statements of Entheon for the fiscal years ended March 31, 2020 (audited) and March 31, 2019 (audited)

Schedule "B" - MD&A of Entheon for the fiscal years ended March 31, 2020 and March 31, 2019

Schedule "C" - Financial Statements of Entheon for the three month period ended June 30, 2020 (unaudited) and June 30, 2019 (unaudited)

Schedule "D" - MD&A of Entheon for the three month period ended June 30, 2020 and June 30, 2019

Schedule "E" - Financial Statements of Former Entheon for the fiscal year ended November 30, 2019 (audited) and the nine-month period ended August 31, 2020 (unaudited)

Schedule "F" - MD&A of Former Entheon for the fiscal year ended November 30, 2019 and the nine-month period ended August 31, 2020

Schedule "G" - Pro Forma Financial Statements of Entheon

**SCHEDULE "A"**

**Financial Statements of Entheon for the fiscal years ended  
March 31, 2020 (audited) and March 31, 2019 (audited)**

## **SCHEDULE “B”**

**Management’s Discussion and Analysis of Enttheon  
for the fiscal years ended March 31, 2020 and March 31, 2019**

**SCHEDULE "C"**

**Financial Statements of Enttheon for the three month period ended  
June 30, 2020 (unaudited) and June 30, 2019 (unaudited)**

**SCHEDULE "D"**

**Management's Discussion and Analysis of Enttheon  
for the three month period ended June 30, 2020 and June 30, 2019**

## **SCHEDULE "E"**

**Financial Statements of Former Entheon for the fiscal year ended November 30, 2019 (audited) and the nine-month period ended August 31, 2020 (unaudited)**

## **SCHEDULE “F”**

**Management’s Discussion and Analysis of Former Enttheon for the fiscal year ended November 30, 2019 and the  
nine-month period ended August 31, 2020**

## **SCHEDULE “G”**

### **Pro Forma Financial Statements of Enttheon**

**CERTIFICATE OF ENTHEON BIOMEDICAL CORP.**

Pursuant to a resolution duly passed by its Board of Directors, Entheon Biomedical Corp. hereby applies for the listing of the above mentioned securities on the Canadian Securities Exchange. The foregoing contains full, true and plain disclosure of all material information relating to Entheon Biomedical Corp. It contains no untrue statement of a material fact and does not omit to state a material fact that is required to be stated or that is necessary to prevent a statement that is made from being false or misleading in light of the circumstances in which it was made.

Dated at Vancouver, British Columbia

this 12th day of November, 2020.

---

**Timothy Ko**  
Chief Executive Officer, President and  
Director

---

**Brandon Schwabe**  
Chief Financial Officer

---

**Christopher Gondi**  
Director

---

**Andrew Hegle**  
Chief Science Officer and Director

---

**Ruth Chun**  
Director

---

**Timothy Ko**  
Promoter

**CERTIFICATE OF ENTHEON BIOMEDICAL CORP.**

The foregoing contains full, true and plain disclosure of all material information relating to Entheon Biomedical Corp. It contains no untrue statement of a material fact and does not omit to state a material fact that is required to be stated or that is necessary to prevent a statement that is made from being false or misleading in light of the circumstances in which it was made.

Dated at Vancouver, British Columbia

this 12th day of November, 2020.

---

**Timothy Ko**  
**Chief Executive Officer and Director**

---

**Brandon Schwabe**  
**Chief Financial Officer and Director**

---

**Christopher Gondi**  
**Director**

---

**Andrew Hegle**  
**Director**

---

**Timothy Ko**  
**Promoter**