Awakn Life Sciences Corp

# AWAKN LIFE SCIENCES CORP.

301-217 Queen Street West Toronto, Ontario M5V 0R2 ANNUAL INFORMATION FORM

For the year ended January 31, 2023

Dated April 27, 2023

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# DEFINITIONS

The following is a list of certain defined terms used throughout this annual information form. This is not an exhaustive list of defined terms used herein and additional terms are defined throughout. Terms used and not defined in this annual information form that are defined or interpreted in the National Instrument 14-101 - Definitions of the Canadian Securities Administrators, bear that definition or interpretation.

"Addiction" means a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences.

"AI" means artificial intelligence.

"AIF" means this annual information form.

"Amalco" means Awakn Life Sciences Inc.

"AUD" means Alcohol use Disorder.

"Audit Committee" means the audit committee of the Board.

"Awakn Bristol" means Awakn Bristol Limited, a company incorporated and registered in England and Wales and is an indirectly wholly-owned subsidiary of the Company.

"Awakn Europe" means Awakn LS Europe Holdings Limited, a company incorporated and registered in Ireland and is an indirectly wholly-owned subsidiary of the Company.

"Awakn Inc." means Awakn Life Sciences Inc., a company incorporated under the OBCA.

"Awakn Ketamine-Assisted Psychotherapy" has the meaning ascribed thereto in the section entitled "*Description of Business – Operations*" in this AIF.

"Awakn Life Sciences UK" means Awakn Life Sciences UK Ltd., a company incorporated and registered in England and Wales and is an indirectly wholly-owned subsidiary of the Company.

"Awakn London" means Awakn London Limited, a company incorporated and registered in England and Wales and is an indirectly wholly-owned subsidiary of the Company.

"Awakn Manchester" means Awakn Manchester Limited, a company incorporated and registered in England and Wales and is an indirectly wholly-owned subsidiary of the Company.

"Awakn Norway" means Awakn Norway AS (formerly Awakn Oslo AS and Axonklinikken AS), a company incorporated and registered in Norway and is an indirectly wholly-owned subsidiary of the Company.

"Awakn Partnerships" means Awakn LS Partnerships Limited, a company incorporated and registered in Ireland and is an indirectly wholly-owned subsidiary of the Company.

"Axon" means Axonklinikken AS.

"Axon Acquisition" means share exchange agreement to acquire a 100% interest in Axon.

"Axon Acquisition Shares" mean an aggregate of 200,000 shares issued to the shareholders of Axon at a deemed price of \$2.50.

"**Axon Additional Consideration**" means payment to the shareholders of Axon additional consideration of up \$1,350,000 based on Axon meeting certain milestones:

- (i) Axon opening a second clinic in Norway;
- (ii) Axon opening a first clinic in a second Nordic (Norway, Sweden, Denmark, Finland or Iceland) country;
- (iii) Axon opening a first clinic in a third Nordic country; and
- (iv) Axon achieving agreed revenue and EBIDTA targets.

"**BCBCA**" means the *Business Corporations Act* (British Columbia), as amended from time to time, including the regulations promulgated thereunder.

"BIMA" means Bristol Imperial MDMA in Alcoholism.

"Board" means the board of directors of the Company as constituted from time to time.

"Bristol Clinic" means Awakn Bristol's clinic located at 1 Regent Street, Bristol BS8 4HW, United Kingdom.

"CADD" means computer aided drug design.

"CBCA" means the *Canada Business Corporations Act*, as amended from time to time, including the regulations promulgated thereunder.

"Common Shares" means the common shares of the Company.

"**Company**" means Awakn Life Sciences Corp., a company existing under the *Business Corporations Act* (British Columbia).

"COVID-19" means Coronavirus disease 2019, an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

"CQC" means Care Quality Commission in the UK.

"EBITDA" means earnings before interest, taxes, depreciation and amortization.

"Exeter Licence" has the meaning ascribed thereto in the section entitled "Description of Business – Operations" in this AIF.

"**IFRS**" means the International Financial Reporting Standards prepared in accordance with International Accounting Standards 34, Interim Financial Reporting, as issued by the International Accounting Standards Board.

"KARE" or "Awakn Kare" means Ketamine for Reduction of Alcoholic Relapse.

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

"**MDMA**" means 3,4-Methylenedioxymethamphetamine.

"MHRA" means Medicines and Healthcare products Regulatory Agency of the United Kingdom.

"NCE" means New Chemical Entity.

"Neo Exchange" means the Neo Exchange Inc.

"NI 52-101" means National Instrument 52-109 – *Certification of Disclosure in the Company's Annual and Interim Filings* of the Canadian Securities Administrators.

"Nutt Research" has the meaning ascribed thereto in the section entitled "Description of Business – Operations" in this AIF.

"**OBCA**" means the *Business Corporations Act* (Ontario), as amended from time to time, including the regulations promulgated thereunder.

"PTSD" means Post-traumatic Stress Disorder.

"R&D" means Research and Development.

"RTO" has the meaning ascribed thereto in the section entitled "Corporate Structure – Incorporation" in this AIF.

"SEDAR" means the System for Electronic Document Analysis and Retrieval, a filing system developed for the Canadian Securities Administrators.

"TRD" means Treatment Resistant Depression.

"United Kingdom" or "UK" means the United Kingdom of Great Britain and Northern Ireland.

"United States", "US" or "USA" means the United States of America.

# **INTRODUCTORY NOTES**

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

The information provided in this AIF, including information incorporated by reference, may contain "forward-looking statements" and "forward-looking information" (collectively referred to hereafter as "**forward-looking statements**") about the Company.

All statements, other than statements of historical fact, made by the Company that address activities, events or developments that the Company expect or anticipate will or may occur in the future are forward-looking statements, including, but not limited to, statements preceded by, followed by or that 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 may relate to future financial conditions, results of operations, plans, objectives, performance or business developments.

These statements speak only as of the date they are made and are based on information currently available and on the then current expectations of the Company and assumptions concerning future events. Forward-looking statements are subject to a number of known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from that which was expressed or implied by such forward-looking statements. Some of the important risks and uncertainties that could affect forward-looking statements are described further under the headings "*Risk Factors*" and in other documents incorporated by reference in this AIF.

In particular, this AIF contains forward-looking statements pertaining to, but not limited to the following:

- expectations regarding the Company's ability to raise capital;
- the impact of the COVID-19 pandemic;
- statements relating to the business and future activities of, and developments related, to the Company to the date of this AIF and thereafter;
- the business objectives of the Company and its research and development activities;
- the acceptance in the medical community of ketamine, MDMA or NCE's as effective treatment for AUD and other mental health conditions;
- the ability of the Company to develop proper protocols to incorporate the use of additional psychedelic medicines as they are legalized and approved for use;
- the ability of the Company to obtain regulatory approvals prior to each clinical trial;
- the ability of the Company to provide effective licensing services;
- potential timelines related to clinical trials, other milestones, and associated results;
- controlled substances laws;
- reliance on third parties;
- liquidity of the Common Shares;
- anticipated developments in the operations of the Company;
- currency fluctuations;
- estimated budgets of the Company;
- the healthcare industry in the United Kingdom, United States, Canada, the European Union and other European countries;
- the ability of the company to attract patients and receive referrals;

- the approval of regulatory bodies of psychedelic substances other than ketamine, including MDMA and NCE's, for the treatment of various health conditions;
- the ability of the Company to complete and operate its clinical expansion; and
- the ability of new clinics to offer ketamine-assisted psychotherapy, psychedelic-assisted psychotherapy, and other services.

Forward-looking statements are based on certain assumptions and analyses made by the Company in light of the experience and perception of historical trends, current conditions and expected future developments and other factors it believes are appropriate and are subject to risks and uncertainties. In making the forward-looking statements included in this AIF, the Company has made various material assumptions, including but not limited to (i) obtaining necessary shareholder and regulatory approvals; (ii) that regulatory requirements will be maintained; (iii) general business and economic conditions including that financial markets will not in the long term be adversely impacted by the COVID-19 pandemic; (iv) the Company's ability to successfully execute its plans and intentions; (v) the availability of financing on reasonable terms; (vi) the Company's ability to attract and retain skilled staff; (vii) receipt and/or maintenance of required licenses and third party consents in a timely manner or at all; and (viii) the success of the operations of the Company.

The actual results could differ materially from those anticipated in these forward-looking statements as a result of the risk factors set forth in this AIF. Consequently, all forward-looking statements made in this AIF and other documents of the Company are 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 the Company. 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 the Company and/or persons acting on their behalf may issue. The Company 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 securities laws. For all these reasons, shareholders should not place undue reliance on forward-looking statements.

# General

Unless otherwise stated, in this AIF:

- information is presented as of January 31, 2023;
- all dollar amounts are in Canadian dollars; and
- references to the "Company", "it", "its", and other related terms refer to Awakn Life Sciences Corp. and its subsidiaries.

# **CORPORATE STRUCTURE**

### Incorporation

The Company was incorporated on June 21, 2018 under the BCBCA under the name 1169082 B.C. Ltd. as a whollyowned subsidiary of Hemagenetics Technologies Corp. ("**HTC**"), then a reporting issuer in the provinces of British Columbia and Alberta. On June 26, 2018, the Company entered into a statutory arrangement with among others, HTC (the "**Arrangement**"). The Arrangement received final B.C. supreme court approval on July 19, 2018. On April 29, 2019, the Company completed the Arrangement and became a reporting issuer in the provinces of British Columbia and Alberta. Effective June 15, 2021, the Company completed a reverse takeover transaction (the "**RTO**") of Awakn Inc. pursuant to which Awakn Inc. amalgamated with a wholly-owned subsidiary of the Company to form Amalco, now a wholly-owned subsidiary of the Company. Upon completion of the RTO, the Company changed its name to its current name, Awakn Life Sciences Corp., and consolidated its issued and outstanding common shares on the basis of one post-consolidation common share for every 42.5105 pre-consolidation common shares. Following completion of the RTO, the Company became a reporting issuer in the provinces of British Columbia, Alberta and Ontario.

The address of the Company's registered and records office is located at Suite 600, 890 West Pender Street, Vancouver, British Columbia, V6C 1J9 and the head office is located at 301-217 Queen St. West, Toronto, ON, M5V 0R2.

The Common Shares started trading on the Neo Exchange on June 21, 2021 under the symbol "AWKN". On August 12, 2021, the Common Shares also started trading on the OTCQB Venture market under the ticker symbol "AWKNF". On August 13, 2021, the Common Shares also started trading on the Boerse Frankfurt exchange under the symbol "954".

### **Intercorporate Relationships**

The Company operates in the UK through its indirectly wholly-owned subsidiaries Awakn Bristol Limited ("Awakn Bristol"), Awakn Life Sciences UK Ltd. ("Awakn UK"), Awakn London Limited ("Awakn London") and Awakn Manchester Limited ("Awakn Manchester"), in Ireland through its indirectly wholly-owned subsidiaries Awakn LS Europe Holdings Limited ("Awakn Europe") and Awakn LS Partnerships Limited ("Awakn Partnership") and in Norway under Awakn Norway AS ("Awakn Norway").

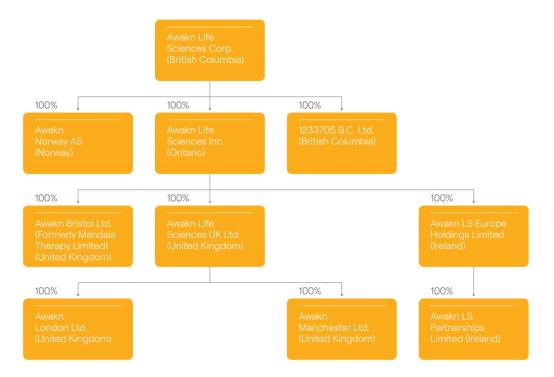
Awakn Bristol was incorporated and registered in England and Wales on June 17, 2016 under the name Mandala Therapy Limited. Mandala Therapy Limited changed its name to "Awakn Bristol Limited", effective November 4, 2020.

Awakn Life Sciences UK was incorporated and registered in England and Wales on July 24, 2020. Awakn London was incorporated and registered in England and Wales on March 1, 2021. Awakn Manchester was incorporated and registered in England and Wales on May 18, 2021.

Awakn Partnerships and Awakn Europe, were incorporated and registered in Ireland on July 7, 2021.

Awakn Norway was incorporated and registered in Norway on May 24, 2018 under the name Axonklinikken AS. Axonkilnikken AS changed its name to "Awakn Oslo AS" on November 16, 2021, and subsequently changed name to "Awakn Norway AS".

The following organizational chart reflects the intercorporate structure of the Company:



# **DESCRIPTION OF THE BUSINESS**

The Company is a revenue-generating biotechnology company developing therapeutics to treat addiction, with a near term focus on Alcohol Use Disorder (AUD), a condition affecting 285 million people globally for which the current standard of care is inadequate. The Company's goal is to provide breakthrough therapeutics to addiction sufferers and our strategy is to commercialize our R&D pipeline across multiple channels.

The Company's core functions are:

# 1. **Research and Development**:

• **Research and Development:** Preclinical and clinical stage programs to develop effective therapeutics to treat addiction with appropriate intellectual property moats.

# 2. **Delivery**

- **Clinics:** Operating a limited number of clinics: to deploy the therapeutics developed in the Company's R&D business; to generate revenue and clinical data, and to provide the latest evidence backed therapeutics to treat addiction and mental health conditions.
- **Licensing Partnerships:** Deliver the Company's proven therapeutics at scale by enabling third party clinics and addiction treatment centres to deploy more effective treatments to their patients.

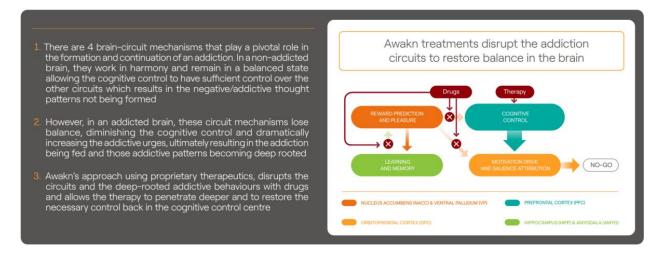
The Company was set up with these separate, but linked, research and development and commercialization functions, for the purposes of making a genuine positive impact on the lives of individuals, their families, and their communities who suffer with addiction, which is at present a poorly treated, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. Those suffering with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.

### Approach to treating Addiction

The Company is addressing addiction by developing proprietary therapeutics (drugs and therapies to be used in combination) to treat addiction.

The Company's therapeutics are focused on the brain circuits that drive addiction, multiple receptors rather than the traditional single drug receptor targets. This focus on circuit mechanisms rather than individual receptors, enables the Company to develop treatments for both substance and behavioural addictions.

The medicines that the Company is researching, developing, and delivering disrupt the connections within and between certain brain circuits. The disruption is intended to allow individuals to escape from the repetitive addictive behaviours and thoughts. However, this induced disruption alone is often not enough to enable lasting positive change, so the Company is also researching, developing and delivering proprietary therapies, which work in conjunction with the medicines to enable patients to regain control over their lives and help to learn new more adaptive ways to respond to addictive urges, cravings and the underlying psychological processes that drive them.



The Company's therapeutics research and development program has three core work streams: ketamine, MDMA, and NCE's. Execution of this program will be accelerated because of the Company's focus on both research and development, and commercialization, because the Company will test and validate its therapies based on real world evidence in addition to clinical trial evidence. The Company's NCE program is currently on hold until the Company's cost of capital is reduced.

# **Research and Development activities:**

Therapeutics Research and Development:

The Company's therapeutics research and development team consists of world leading experts in the fields of drug development, clinical research, psychiatry, and psychotherapy who are building the next generation pipeline of new medicines and therapies, which are focused on treating substance and behavioural addictions.

The Company's drug and therapy research and development and intellectual property portfolio is split into:

- 1. Repurposing racemic ketamine (Intravenously (IV)) + therapy to treat Severe Alcohol Use Disorder (AUD), which affects 70 million people globally;
- 2. Repurposing (S)-ketamine (Sub-lingually (SL)) and therapy to treat Mild AUD and Moderate AUD, which affect 215 million people combined globally;
- 3. Repurposing (S)-ketamine (SL) and therapy to treat behavioral addictions;
- 4. Developing MDMA to be used in combination with therapy to treat addiction, including developing MDMA onto Catalent's for Zydis® Technology, Oral Disintegrating Tablet (ODT); and
- 5. Developing NCE's that will disrupt the brain circuits responsible for the addictive behaviours of compulsivity, craving, and impulsivity and will improve the effectiveness of psychotherapy but will work in shorter treatment windows, which is currently on hold.

Short term focused IP and development projects:

- The Company has acquired an exclusive license to the intellectual property from the University of Exeter's Phase II ab Ketamine for reduction of Alcoholic Relapse ("KARE") clinical trial results, which showed an 86% abstinence on average over the six month period post treatment. The Company is delivering the proprietary therapy in its clinics and has signed several licensing partnerships in the USA and Canada allowing other clinics to also deliver the proprietary therapy.
- The Company has signed a Collaboration Agreement with the University of Exeter putting in place a framework for the upcoming Phase III trial for the use of ketamine-assisted therapy to treat Severe AUD. The trial will be n=280, two-armed randomized placebo-controlled trial. It will be delivered across ten NHS sites, and Awakn will contribute approximately GBP800,000 towards the costs of the trial, with the National Institute for Health Care Research and Medical Research Counsel and University of Exeter contributing the balance of the costs.
- The Company has also completed a mechanistic study assessing Ketamine in Gambling Disorder and other behavioural addiction. The data from this study enabled the Company to file a Patent Cooperation Treaty (PCT) application for the treatment of behavioral addictions with ketamine and ketamine-assisted psychotherapy. If granted, the patent claims would give Awakn exclusive rights to use ketamine and ketamine-assisted therapy for the treatment of behavioral addictions

Medium term focused IP and development projects:

- The Company has signed a twelve-month option agreement with a leading drug development, manufacturing, and delivery systems company to in-license a proprietary formulation and route of administration for ketamine. The formulation and route of administration will be optimized for commercialization and has the potential to deepen the intellectual property (IP) moat for Awakn's lead clinical development program Project Kestrel, which targets AUD.
- The Company has signed a drug development agreement with Catalent for Zydis® Technology (an orally disintegrating tablet) to conduct feasibility studies to improve differentiation of its MDMA program. Zydis is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water and has a dispersion speed of as little as three seconds. The agreement will allow Awakn to conduct feasibility studies using Zydis technology for addiction, including substance and behavioural addictions, as well as other mental health disorders, including anxiety, depression, post-traumatic stress disorder (PTSD), and eating disorders.

Long term focused IP and development projects:

- The Company is developing the next generation of medicines to better treat addiction.
- The Company acquired five years of know-how and research data from Prof. David Nutt's Equasy Enterprises Ltd ("Equasy Enterprises"), as defined herein, in March, 2021. In this acquisition the Company acquired two key assets:
  - Details of potentially newly discovered modes of action for MDMA
  - Details of potentially faster acting entactogen like compounds
- The Company initiated a drug discovery project with Evotec A.G. ("Evotec") in June 2021, which includes all activities from identification and production of initial molecules, screening in vitro and in vivo, demonstration of MDMA-like pharmacological properties, med chem delivery of analogues, preliminary formulation, evaluation of brain penetration, absorption, distribution, metabolism and excretion ("ADME"), efficacy in vivo, and selectivity.
- The Company has filed four patent applications for next-generation novel MDMA-derived new chemical entities;
- The Company has currently paused most of its long term focused development projects to focus its capital resources on its short term and medium term projects.

# **Development Pipeline:**

INDICATION	COMPOUND	PRECLINICAL DEVELOPMENT	CLINICAL DEVELOPMENT PHASE	PHASE I	PHASE II a	PHASE II b	PHASE III
LEAD CLINICAL DEVELOPMENT PROGRAM - PROJECT KESTREL							
SEVERE AUD	Racemic ketamine (IV)	_	_	-	-		•
MILD AND MODERATE AUD	(S)-ketamine (SL)	_					
BEHAVIORAL ADDICTIONS	(S)-ketamine (SL)						
SECONDARY PROGRAM							
AUD	MDMA	_		_	_		
MULTIPLE	MDMA/Zydis (SL)	_					
						Acquired	live Research

# Commercialization

The Company is, and will, commercialize its R&D pipeline through two channels:

1. Clinics:

The Company currently owns and operates four clinics in the UK and Norway (the fourth opened post year end in Trondheim Norway). The Company may assess future clinic expansion at a future date. The Company's clinical activity is focused on treating clients who are in need of assistance with addiction and other mental conditions including Anxiety, Depression, and PTSD, with psychedelic-assisted psychotherapy, starting with ketamine-Assisted Psychotherapy while focusing on:

- Developing proprietary therapies to be used in combination with drugs to treat addiction and to drive R&D
- Generating revenue; and
- Generating real world evidence.

The Company's clinicians work collaboratively with clients to understand their difficulties, expectations and objectives, to formulate a treatment plan that is tailored to each client. Dose ranges vary from lower doses in which self-reflection and psychological flexibility are notably improved, and a higher dose in which the client has a more intense, internal experience with integrative therapeutic support following the drug-assisted sessions. Integration sessions are targeted to occur at the point of peak neuroplasticity following a drug-assisted session, and provide an opportunity for a client to process their experience, explore insights and lay the foundation for functional change in their lives.

Another key differentiation of the Company's approach is to target the underlying cause of the client's presenting issue, which is often trauma, rather than traditional addiction treatment approaches, which focus on treating the symptoms. The Company believes that symptom suppression is not a cure, which is why the Company aims to focus on the root of the issue.

The chart below sets out the status and target opening date of each clinic:

Location	Size (Sq Ft)	Status	Target Opening Date (Calendar Quarter)	Number of Treatment Rooms
Bristol, UK	1,384	Open	-	3
Oslo, Norway	1,528	Open <sup>(1)</sup>	-	2
London, UK	4,419	Open	-	8
Trondheim, Norway	1,400	Open <sup>(2)</sup>	-	3

 Acquired on October 4, 2021 – the Company is in progress of opening up a larger Oslo clinic which will have 6 treatment rooms, targeting May, 2023. The two room clinic will be shut down at that point in time.

(2) Opened in March, 2023

2. Licensing Partnerships:

The Company's licensing partnerships activity is focused on commercializing the Company's therapeutics beyond the Company's clinics. Starting with licensing the Company's proprietary Ketamine-Assisted Therapy for the treatment of Alcohol Use Disorder (AUD) to addiction treatment centers in territories where the Company does not operate clinics.

The core elements to the Company's partnership offering:

- Licensing: Access to Awakn proprietary Ketamine-Assisted Psychotherapy treatment protocols and therapy manuals, starting with the Awakn Kare (Ketamine for reduction of Alcoholic Relapse) treatment program.
- **Training:** Online and in person training for practitioners delivering the Awakn Kare treatment program under license.
- Systems: Access to policies, protocols and technologies.
- **Design:** Assistance with optimizing the design of the physical environment where the therapy takes place.

To date, the Company has signed five licensing agreements, of which three are in the United States, one in Canada and one in Portugal. Subsequent to year end, the first patients received the Awakn Kare treatment from the Company's New York based licensing partner, Nushama Inc. The licensing agreement the Company signed in Portugal was for 10 years on an exclusive basis for all of Portugal, and included Awakn's protocols for not just Awakn Kare, but also included protocols to treat Anxiety, Depression, Eating Disorders and PTSD.

# **GENERAL DEVELOPMENT OF THE BUSINESS**

# Overview

The Company did not carry on any business until the completion of the RTO. Upon completion of the RTO, the Company started carrying on the business of Awakn Inc., a biotechnology company with clinical operations, researching, developing and delivering of psychedelic medicine to treat addiction and other mental health conditions.

# **Three-Year History**

The following is a summary of the general development of the Company's business over the past three years.

# Financial Year Ended January 31, 2021

On June 16, 2020, Awakn Inc. (now, Amalco), Dr. Ben Sessa and Awakn Bristol entered into an investment agreement (the "Awakn Bristol Investment Agreement") to acquire from Dr. Sessa an interest in Awakn Bristol (the "Awakn Bristol Acquisition"). In connection with the Awakn Bristol Acquisition, the parties to the Awakn Bristol Agreement entered into a shareholders' agreement (together with the Awakn Bristol Investment Agreement, collectively the "Awakn Bristol Acquisition Arrangements"). Pursuant to the Awakn Bristol Acquisition Arrangements, effective November 30, 2020, Awakn Inc. acquired a 51% interest in Awakn Bristol for (i) cash consideration of £325,000 invested in two installments (as to £74,000 invested on July 9, 2020 and as to £250,330 invested on November 30, 2020); and (ii) the issue of 3,000,000 common shares of Awakn Inc. with a fair value of \$60,000 at \$0.02 per common

share of Awakn Inc. (issued on July 6, 2020) to Dr. Sessa. Pursuant to the Awakn Bristol Acquisition Arrangements, Awakn Inc. has the option to acquire Dr. Sessa's remaining 49% ownership interest in Awakn Bristol by paying Dr. Sessa the greater of \$2,000,000 and the fair value, determined in accordance with the terms of the Awakn Bristol Acquisition Arrangements (the "**Awakn Bristol Option**"). Awakn Inc. may only exercise the Awakn Bristol Option upon completion of a liquidity event. Under the Awakn Bristol Acquisition Arrangements, Dr. Sessa has a put option to force Awakn Inc. to acquire his 49% ownership interest in Awakn Bristol which may only be exercised in conjunction with a liquidity event, which was subsequently cancelled. All Awakn Bristol Option payments are payable in Common Shares. At the time of the entering into of the Awakn Bristol Investment Agreement, Dr. Sessa, now the Chief Medical Officer, a director and a member of the Clinical Advisory Board of the Company, was at arm's length with Awakn Inc.

On July 6, 2020, Awakn Inc. appointed Professor David Nutt as the chair of its scientific advisory board.

On August 31, 2020, Awakn Inc. appointed Professor Matthew Johnson as a member of its scientific advisory board.

On September 2, 2020, Awakn Inc. signed a lease for its first clinic, the Bristol Clinic, which is located at 1 Regent Street, Bristol BS8 4HW, United Kingdom.

On September 21, 2020, the Company appointed Professor Celia Morgan as a member of its scientific advisory board.

On September 22, 2020, the Company appointed Dr. Michael Mithoefer and Ann Mithoefer as members of its scientific advisory board.

On November 30, 2020, Awakn Inc. completed its seed round financing, raising gross proceeds of \$1,000,000.

On December 18, 2020, Awakn Inc. appointed Professor Celia Morgan as Ketamine-Assisted Psychotherapy for Alcohol Use Disorder Leader.

On January 1, 2021, Awakn Inc. appointed James Collins as Chief Operating Officer, now the Chief Operating Officer of the Company.

On January 11, 2021, Awakn Inc. appointed Dr. Shaun McNulty as Chief Science Officer, now the Chief Science Officer of the Company.

### Financial Year Ended January 31, 2022

On March 1, 2021, Awakn Inc. acquired from the University of Exeter an exclusive licence to use and deliver the Ketamine in the Reduction of Alcoholic Relapse psychotherapy intervention, as validated in a Phase II clinical trial led by the University of Exeter. The research will allow the Company and potential licensing partners to treat clients with a research backed treatment for AUD.

On March 3, 2021, the Company and Awakn announced their intention to complete the RTO and the listing of the Common Shares on the Neo Exchange.

On March 8, 2021, Awakn Inc. completed the acquisition of five years of proprietary research data on next generation candidate MDMA and Ketamine molecules ("**IP** Assets") from Equasy Enterprises Ltd. ("**Equasy Enterprises**"), a company established and controlled by Professor David Nutt, now the Chief Research Officer and the chair of each of the Preclinical Advisory Board and the Clinical Advisory Board of the Company, for an aggregate purchase price of \$60,000, payable by the issue of 50,000 common shares of Awakn Inc. at a deemed price of \$1.20 per share. In the event that a patent is filed in the name of Awakn Inc. or a successor company for a next generation molecule that is created using the IP Assets, Awakn Inc. is required to issue to Equasy Enterprises 50,000 shares at a deemed price of \$1.20 per share. The data acquired provides significant insights into the pharmacological mechanisms of action for MDMA. Subsequently, Awakn Inc. signed an amendment to the agreement with Equasy Enterprises, under which it agreed to issue Equasy Enterprises up to an additional 280,000 shares upon the successful completion of certain milestones.

On March 8, 2021, Awakn Inc. appointed Professor David Nutt as Head of Research, to pursue new molecular entities based on the research acquire from Equasy Enterprises. Subsequently on June 24, 2021, the Professor David Nutt was appointed the Chief Research Officer of the Company.

On March 19, 2021, Awakn Inc. completed a convertible debenture financing raising gross proceeds of \$4,000,000. These convertible debentures were subsequently converted into an aggregate of 3,382,095 Common Shares in connection with the completion of the RTO.

On April 9, 2021, Awakn Inc. entered into a non-binding Collaborative Working Agreement with the University of Exeter to set the framework for shared activity on a number of mental health care advanced predictive analytics projects. The Company is now negotiating a contract with the University of Exeter to use a pattern classifier to detect identity shifts following Ketamine treatments through developing digital signatures of identity shifts in recovery for people with problematic substance use.

On April 27, 2021, Awakn Inc. selected Evotec as its NCE research partner.

On May 13, 2021, the Company and Awakn Inc. entered into the definitive binding agreement relating to the RTO.

On June 8, 2021, Awakn Inc. completed, as a condition of the RTO, a private placement of 3,320,220 subscription receipts ("**Subscription Receipts**") at a price of \$2.50 per Subscription Receipt for aggregate gross proceeds of \$8,300,550, which proceeds were held in escrow and released upon completion of the RTO on June 16, 2021. In addition, upon completion of the RTO, each Subscription Receipt was converted into one Common Share for an aggregate of 3,320,220 Common Shares.

On June 11, 2021, each of the Company and Awakn Inc. obtained the applicable shareholder approvals relating to the RTO.

On June 15, 2021, the Company and Awakn Inc. completed the RTO and received the approval of the Neo Exchange for the listing of the Common Shares on the Neo Exchange.

On June 23, 2021, the Common Shares began trading on the Neo Exchange.

On June 24, 2021, the Company announced the appointment of Professor David Nutt as Chief Research Officer.

On June 28, 2021, the Company announced the filing of patent applications in the United States for two nextgeneration novel MDMA-derived new chemical entities, further strengthening the Company's intellectual property portfolio and pipeline for the treatment of a broad range of addictions, including, but not limited to alcohol, opioid and behavioural, such as gambling.

On July 7, 2021, the Company reorganized its existing scientific advisory board by dividing it into two separate preclinical and clinical expert advisory boards to be chaired by Professor David Nutt, the Chief Research Officer of the Company. The Preclinical Advisory Board, which will focus on the R&D, will be Dr. Shaun McNulty, the Chief Scientific Officer of the Company, and newly appointed Professor Stephen Husbands (Professor of Medicinal Chemistry in Department of Pharmacy and Pharmacology at the University of Bath), Professor Harriet de Wit (Professor and Director of the Human Behavioral Pharmacology Laboratory, Department of Psychiatry at the University of Chicago) and Professor Kevin Fone (Professor of Neuroscience at the University of Nottingham). The Clinical Advisory Board now consists of Dr. Benjamin Sessa (Awakn Chief Medical Officer), Professor Celia Morgan (Professor of Psychopharmacology at the University of Exeter and Awakn's Head of Ketamine-Assisted Psychotherapy for Addiction), Ann Mithoefer (Multidisciplinary Association for Psychedelic Studies ("**MAPS**")), Dr. Michael Mithoefer (MAPS) and Professor Matt Johnson (Professor of Psychiatry and Behavioural Sciences at John Hopkins), all of whom were members of the scientific advisory board of the Company prior to its reorganization.

On July 14, 2021, the Company announced that it will undertake a program of clinical research designed to demonstrate the effectiveness of ketamine-assisted psychotherapy against multiple addictions, initially focusing on treating AUD and gambling addiction. The program will consist of, amongst other activities, a late-stage clinical trial

focused on AUD, a mechanistic study focused on gambling addiction and intellectual property development activities. The program was designed and will be led by Professor Celia Morgan, Professor of Psychopharmacology at the University of Exeter, U.K., an internationally respected expert in the therapeutic use of ketamine and the Company's Head of Ketamine-Assisted Psychotherapy for Addiction.

On July 22, 2021, the Company appointed Professor Barbara Mason (Director of the Pearson Center for Alcoholism and Addiction Research, Director of the Laboratory of Clinical Psychopharmacology, and the Pearson Family Professor in the Department of Molecular Medicine at the Scripps Research Institute, La Jolla, CA) to its clinical advisory board.

On July 26, 2021, the Company commenced trading on the OTC Market in the United States under the symbol "AWKNF". Subsequently on August 12, 2021, the Company became qualified to trade on the OTCQB® Venture Market ("OTCQB"). Subsequently on September 1, 2021, the Company obtained DTC Eligibility for shares to be electronically cleared and settled in the United States.

On August 4, 2021, the Company signed a 10-year lease to open Awakn clinics in London ("**Awakn Clinics London**"), a psychedelic-focused therapy center to treat addiction and other mental health conditions. Awakn Clinics London is expected to be approximately 4,419 square-feet and will host eight treatment rooms. The Company has partnered with One Fine Day Design Limited, specialists in designing places that deliver meaningful outcomes and better connections for a brand's audience, creating places, not spaces. Awakn Clinics London will be designed to offer a warm and welcoming experience to demonstrate first-hand how psychedelics can transform the lives of clients. Following a client-centered design approach, the clinic space will showcase an evidence-based environmental design focused on client wellbeing and supports the right context for effective treatment. The clinic is located on Duke's Road, near the UCL Hospital and the British Medical Association.

On September 23, 2021, the Company announced that it has acquired the exclusive rights to the data from the Phase IIa Bristol Imperial MDMA in Alcoholism Study ("**BIMA**") from Imperial College London. BIMA is an Open-label safety, tolerability and proof-of-concept study to investigate the role of MDMA Assisted Psychotherapy in treating patients with alcohol use disorder ("**AUD**"). BIMA was the first published study assessing MDMA-Assisted Psychotherapy as a treatment for addiction. The results, which were published in February 2021, indicated that MDMA has the potential to be more effective at treating AUD, with a 20% relapse rate within the first nine months, compared to 75% relapse rate with traditional treatments. The Company believes that this data will assist the Company's progress by enabling a better design and more efficient execution of its clinical program. The Company will now be able to accelerate its clinical research into a Phase IIb randomized controlled trial in the U.K.

On October 4, 2021, the Company completed the acquisition of Axon (the "Axon Acquisition"). In connection with the Axon Acquisition, the Company issued to the shareholders of Axon an aggregate of 200,000 Common Shares (the "Axon Acquisition Shares") at a deemed price of \$2.50 per Axon Acquisition Share. The Axon Acquisition Shares are subject to a lock-up resulting in 10% of the Axon Acquisition Shares having been released immediately on closing of the Axon Acquisition and 15% of the Axon Acquisition Shares will be released every three months thereafter. The Company has also agreed to pay to the shareholders of Axon additional consideration of up \$1,350,000 (the "Axon Additional Consideration") based on Axon meeting certain milestones: (i) Axon opening a second clinic in Norway; (ii) Axon opening a first clinic in a second Nordic (Norway, Sweden, Denmark, Finland or Iceland) country; (iii) Axon opening a first clinic in a third Nordic country; and (iv) Axon achieving agreed revenue and EBIDTA targets. The Company has the option to pay any amount of the Additional Consideration in cash or Common Shares at its option. The value to calculate the number of the Common Shares to be issued will be the greater of (i) a 10-day volume weighted average price of the Common Shares, (ii) the minimum price allowable by the NEO Exchange, and (iii) \$2.50 per Common Share. Upon completion of the Axon Acquisition, Axon's name was changed to "Awakn Oslo AS", then subsequently to "Awakn Norway AS" and Dr. Lowan Stewart, Axon's major shareholder, was appointed as Regional Director for the Nordics and Managing Director of Awakn Norway. The Company intends that the Awakn Norway clinic will serve as the Nordic hub from which the Company plans to expand its clinical network across the region. Awakn Norway, led by Dr. Stewart, will be focused on delivering ketamine-assisted psychotherapy for patients and eventually will incorporate ketamine in the Reduction of Alcoholic Relapse' psychotherapy intervention, validated in a Phase II ab clinical trial led by the University of Exeter.

During October, 2021, the Bristol Clinic received its Care Quality Commission's ("CQC") license and its schedule 2

controlled drugs license from the Home Office to begin Ketamine treatments.

On October 28, 2021, the Company announced the success of Phase I of its new chemical entity development program with Evotec, to strengthen the Company's pipeline for the treatment of a broad range of both substance and behavioral addictions. Using AI and CADD approaches, novel MDMA-like new-chemical-entities chemical series' have been identified. Multiple compounds have been tested in vitro, demonstrating drug-like properties including key components of our target product profile. In total seven chemical series have been identified and three leading compounds have been taken into in vivo efficacy analysis. Two chemical series will be utilized in additional phases of preclinical drug discovery that constitute lead optimization. The data generated will be used to support patent applications and to facilitate the development of preclinical development candidates for clinical development.

On November 16, 2021, the Company signed a memorandum of understanding with Devon Partnership NHS Trust ("**NHS**") and the University of Exeter creating a collaboration (the "**NHS Collaboration**") with a view of increasing access to psychedelic-assisted psychotherapy in the UK, with a focus on bringing the Phase II A/B Ketamine-Assisted Therapy for Treatment of Alcohol Use Disorder ("**KARE**") clinical trial into Phase III. The NHS Collaboration establishes a framework and strategic relationship to assess NHS' organizational readiness for ketamine-assisted psychotherapy as an alternative treatment for AUD and treatment-resistant depression within the NHS. The NHS Collaboration will also assess how best to accelerate the on-label use of ketamine-assisted psychotherapy to treat AUD at scale.

On November 30, 2021, the Company announced that it has executed an agreement (the "**Butler Agreement**") to appoint Katherine Butler as Chief Financial Officer, and that Jonathan Held, the current Chief Financial Officer, will transition to the position of Chief Business Officer. Under the terms of the Butler Agreement, Jonathan Held will maintain his position as the Chief Financial Officer for a transition period of up to three months (or such period as may be agreed by the parties to the Butler Agreement).

On December 14, 2021, the Company announced the appointment of Paul Carter, Former Executive Vice-President and Chief Commercial Officer of Gilead Sciences, Inc. as an independent member of the board of directors of the Company. Mr. Carter replaced Dr. Ben Sessa who has resigned from the board of directors of the Company, but remains in his position as the as Co-Founder and Chief Medical Officer of the Company.

On January 5, 2022, the Company announced the expansion of its study of Ketamine for gambling disorder to also include three other behavioral addictions including Binge Eating Disorder, Compulsive Sexual Behavior and Internet Gaming Disorder. The study will be led by Prof. Celia Morgan, the Company's Head of Ketamine Assisted Therapy for Addiction and Professor of Psychopharmacology at the University of Exeter. Prof. Morgan's work will investigate a new treatment approach for these behavioral addictions, trying to harness a window in which the brain is able to make new connections. The study will explore and monitor whether the ketamine can increase neuroplasticity using electroencephalogram.

On January 11, 2022, the Company announced positive results from Phase II A/B KARE trial. KARE trial was the world's first controlled clinical trial to investigate Ketamine-Assisted Therapy for the treatment of AUD, the results of which have been published in the American Journal of Psychiatry. The trial was conducted by the University of Exeter and led by Prof. Celia Morgan, the Company's Head of Ketamine Assisted Therapy for Addiction and Professor of Psychopharmacology at the University of Exeter. The Company acquired the intellectual property to the therapy under license for use in further research, its clinics in Europe and its partnerships globally.

The double-blind placebo-controlled KARE trial included 96 patients with severe AUD, who were randomized to one of four groups: (1) three ketamine infusions (0.8 mg/kg IV over 40 minutes) plus proprietary manualized therapy; (2) three saline infusions plus KARE therapy; (3) three ketamine infusions plus alcohol education; and (4) three saline infusions plus alcohol education. The primary outcomes of the KARE trial were (1) days abstinent in the six month period after treatment and (2) relapse at six month follow up.

The findings of the KARE trial showed that ketamine combined with KARE therapy, resulted in total abstinence in 162 of 180 days in the following six-month period, achieving an increase in abstinence from around 2% prior to the trial to 86% post trial. The results for relapse at six months showed that the Ketamine plus KARE group's risk of

relapse was 2.7 times less than the placebo plus alcohol education group. The secondary findings of the KARE trial identified further encouraging results including improved liver function across several different markers, a statistically significant decrease in depression after three months and an increase in the ability to experience pleasure.

In addition to the primary and secondary findings of the KARE trial, Prof. Morgan identified further significant results in the reduction in heavy drinking days. At six months' post trial, there was an average of 12 heavy drinking days in the Ketamine plus KARE group, this is a large reduction compared to other trials in this area and it is widely believed the real-world data is far higher than this. Within the KARE group there was also a significant decrease in the risk of mortality, one in eight patients would have died within 12 months without treatment, that number decreased to one in 80 following the treatment.

The KARE trial demonstrated that three subanesthetic infusions of ketamine support abstinence from alcohol and that abstinence may be further enhanced when ketamine treatment is combined with therapy. No serious adverse events took place during the trial.

On January 19, 2022, the Company announced the signing of a memorandum (the "**MAPS MOU**") of understanding with the Multidisciplinary Association for Psychedelic Studies ("**MAPS**") to explore a partnership for MDMA-assisted therapy for the treatment of AUD in Europe. Under the terms of the MAPS MOU, the Company will explore a data licensing agreement with MAPS to support the Company's Phase IIb and planned Phase III studies for MDMA-assisted therapy for AUD in Europe. The Company and MAPS will also assess a partnership to secure marketing authorization/regulatory approval for the ethical commercialization of MDMA-assisted therapy for the treatment of AUD in Europe. The Company and MAPS will also assess a partnership to secure marketing authorization/regulatory approval for the ethical commercialization of MDMA-assisted therapy for the treatment of AUD in Europe. The MOU was subsequently terminated.

# Financial Year Ended January 31, 2023

On January 26 and February 17, 2022, the Company announced the filing of patent applications for a new chemical series of entactogen-like molecules, further strengthening the Company's intellectual property portfolio and pipeline for the treatment of a broad range of addictions including, but not limited to, substance addictions, such as alcohol, and behavioural addictions, such as a gambling disorder and compulsive sexual behaviour.

In March, 2022, the Company received its final CQC approval, as well as Schedule 2 license for its London clinic, and in April started treating patients.

On March 15, 2022, the Company announced the appointment of Kevin Lorenz as its United States head of commercial development. Mr. Lorenz will lead the Company's therapeutics commercialization activities in the United States, starting with the launch of its licensing partnership for the Company's proprietary methodology of ketamine assisted therapy to treat alcohol use disorder.

On March 17, 2022, the Company announced that it had received regulatory approval for its flagship clinic in London to begin delivering treatments. This is the Company's third clinic, adding to the Company's two operating clinics located in Bristol (UK) and Oslo (Norway).

On March 22, 2022, the Company completed a non-brokered private placement through the issuance of 2,031,250 units at a price of \$1.60 per unit for gross proceeds of \$3.25 million. Each unit was comprised of one Common Share and one half of one Common Share purchase warrant. Each whole warrant is exercisable to acquire one Common Share at a price of \$2.20 for a period of two years.

On April 6, 2022, the Company announced the successful completion of Phase I of its NCE drug discovery program. The Company completed a hit to lead program which delivered its key goals of identifying and patenting novel chemistry scaffolds. It also established drug discovery assays with the potential to facilitate lead optimization activities. This is an essential first step on the pathway of developing new, faster-acting and safer entactogenic therapies for the market. A combination of computational screening and medicinal chemistry approaches was utilized to identify numerous chemical scaffolds via in vitro pharmacology and DMPK ("**DMPK**") testing. Multiple patents have now been filed with several of these chemical scaffolds, demonstrating in vivo activity, providing an excellent starting point for lead optimization activities.

On May 19, 2022, the Company announced the completion of the world's first Ketamine study for a range of behavioral addictions. The behavioral addictions included in the study were Gambling Disorder, Internet Gaming Disorder, Binge Eating Disorder and Compulsive Sexual Behavior. The study investigated Ketamine as a new treatment approach for these behavioral addictions by opening a window in which the brain can make new connections to change behavior. The results from the study indicate the desired effects via potentially novel mechanisms and these results merit a larger study and further exploration, which Awakn is now initiating. The study also supports Awakn's Intellectual Property (IP) strategy and existing filed patent applications, positioning Awakn as a leading company in the behavioral-addiction therapeutic research and development industry. The company expects to update investors further on its IP strategy in the coming weeks.

On May 17, 2022, the Company announced that Dr. Arun Dhandayudham was appointed the Chief Medical Officer of the Company and Dr. Ben Sessa became the Company's Head of Psychedelic Medicine.

On May 26, 2022, the Company announced the filing of a Patent Cooperation Treat (PCT) application for the treatment of behavioral addictions with Ketamine and Ketamine-assisted psychotherapy. The PCT covers all behavioral addictions or any recognized disorder or condition with similar compulsive symptoms to those in the study.

On June 2, 2022, Awakn initiated a follow-on behavioural study investigating Ketamine as a treatment for Gambling Disorder. The study will be the first investigation globally to explore this technique to treat Gambling Disorder and follows the completion of a successful pilot study for a range of behavioural addictions and the filing of a Patent Cooperation Treaty (PCT) for the treatment of behavioural addictions with Ketamine and Ketamine-assisted psychotherapy. The larger study will include 42 patients who are suffering from Gambling Disorder and will see participants undergo a memory reactivation procedure, which is designed to weaken the link between reward and addiction memories.

On June 7, 2022, the Company announced that Dennis Purcell was appointed the special advisor to the Chief Executive Officer of the Company.

On July 15, 2022, the Company announced that it had initiated its Innovative Licensing and Access Pathway ("ILAP") application for its lead program Project Kestral. The ILAP is a UK government run initiative that supports innovative approaches to the safe, timely and efficient development of medicines, which Awakn is applying for in order to accelerate the time to market for its ketamine-assisted therapy for AUD.

On July 20, 2022, the Company announced that the National Institute for Health and Care Research, a UK government agency, has approved grant funding for 66% of the costs of Awakn's Phase III clinical trial exploring the use of ketamine-assisted therapy for the treatment of AUD, which is targeted to be a pivotal trial. The trial is currently forecast to cost approximately CA\$3.75 million in total, with Awakn funding approximately CA\$1.25 million of that. Awakn will partner with the University of Exeter and the UK's National Health Service to deliver the landmark trial. It is planned to be conducted across seven sites in the UK, with the treatment being administered within the NHS infrastructure. The trial is currently designed to include 280 patients and they will be followed up over the course of six to 12 months. The trial will also pilot bespoke ongoing peer support groups post-treatment.

On July 31, 2022, Ms. Kate Butler resigned as the Chief Financial Officer of the Company. Mr. Jonathan Held was appointed Interim Chief Financial Officer in her stead.

During August, 2022, the Company signed two licensing agreements, one with USA based Revitalist Lifestyle and Wellness Ltd., and another with Canadian based Wellbeings® Pain Management and Dependency Clinic, who are in the process of being trained to deliver KARE therapy. Awakn shall be compensated on a revenue share basis. On August 25, 2022, the Company signed a twelve-month option agreement with a leading drug development, manufacturing, and delivery systems company to in-license a proprietary formulation and route of administration for ketamine. The formulation and route of administration will be optimized for commercialization and has the potential to deepen the intellectual property (IP) moat for Awakn's lead clinical development program Project Kestrel, which targets AUD.

On September 12, 2022, the Company signed a drug development agreement with Catalent for Zydis® Technology (an orally disintegrating tablet) to conduct feasibility studies to improve differentiation of its MDMA program. The agreement will focus on investigating a market-ready proprietary formulation and optimized delivery route for MDMA. Zydis is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water and has a dispersion speed of as little as three seconds. Zydis is the world's fastest and best-in-class orally disintegrating tablet and has the potential to deliver a faster onset of activity. Awakn plans to use Zydis technology in its late stage MDMA-assisted therapy clinical trials. The agreement will allow Awakn to conduct feasibility studies using Zydis technology for addiction, including substance and behavioural addictions, as well as other mental health disorders, including anxiety, depression, PTSD, and eating disorders.

On September 14, 2022, the Company closed of the first tranche of a non-brokered private placement financing through the issuance of 1,880,454 units for gross proceeds of \$1,034,250. Each unit was comprised of one (1) Common Share and one (1) Common Share purchase warrant entitling the holder thereof to acquire one Common Share at a price of \$0.68 per Common Share until the date that is twenty-four (24) months from the date of issuance. The first tranche constituted a related party transaction within the meaning of Multilateral Instrument 61- 101 - *Protection of Minority Security Holders in Special Transactions* ("**MI 61-101**") as Professor David Nutt, and Jonathan Held, related parties to the Company under MI 61-101, subscribed for an aggregate of 85,000 units. On November 17, 2022, the Company closed the second and final tranche of the private placement through the issuance of an additional 3,395,812 units at a price of \$0.55 per Unit for additional gross proceeds of \$1,867,697. Concurrently with the closing of the second tranche, the Company settled debt in the aggregate amount of \$154,750 through the issuance of an additional 281,364 units. In total, the Company issued 5,557,630 units at \$0.55 for a total value of \$3,056,697. The Company paid certain eligible persons a cash commission of \$32,010 and issued a total of 53,200 non-transferable finders warrants entitling the holders to purchase one (1) Common Share for a period of two years from the date of issuance at a price of \$0.68 per Common Share.

On October 25, 2022, the Company's wholly-owned subsidiary, Awakn Norway AS (Awakn Norway), entered into a debt financing agreement (the "Loan Agreement") with TD Veen (the "Lender"), a family-owned, Norwegian investment company and current shareholder of Awakn. Pursuant to the Loan Agreement, the Lender has advanced \$781,800 (NOK 6,000,000) bearing interest at a rate of 9% per annum and is secured against Awakn Norway's assets. The Lender shall also receive royalty payments of 2.5% of Awakn Norway's revenues for a five-year period and warrants to purchase up to 600,000 common shares of Awakn at an exercise price of \$0.68 per share for a period of two years.

On November 9, 2022, the Company announced it had signed its third Licensing Partnership agreement in North America. The agreement is with Nushama to bring Awakn's KARE therapy for AUD to Nushama's clinic in New York City (NYC).

During November, 2022, the Company signed new leases for two clinics in Norway, consisting of a three-room clinic in Trondheim, and a six-room clinic in Oslo. The new six-room clinic in Oslo will replace the Company's current two room clinic in Oslo.

On December 13, 2022, the Company announced that its Phase III clinical trial exploring the use of ketamine-assisted therapy for the treatment of severe AUD will be delivered across seven NHS sites in the UK. The trial has also been approved for grant funding for ~66% of the costs by the National Institute for Health and Care Research (NIHR), a U.K. government agency. It is currently forecasted that the trial will cost approximately CA\$3.75 million in total, with the Company funding approximately CA\$1.25 million of that.

On January 24, 2023, the Company announced it has initiated an investigative study to establish the dissociative effect of a proprietary and patent pending formulation of (S)-ketamine delivered via an oral thin film. If the results of this study are positive, it will potentially lead to a global licensing agreement for phase I data of the patent pending oral thin film (S)-ketamine formulation. This could result in Awakn advancing to a larger phase II b study and having global exclusivity rights to use the thin film formulation in the treatment of all addictions.

### Recent Events

On February 7, 2023, the Company announced the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has granted Awakn an Innovation Passport as part of the Innovative Licensing and Access Pathway (ILAP) for its proprietary ketamine-assisted therapy for the treatment of Severe Alcohol Use Disorder. ILAP aims to accelerate time to market, facilitating patient access. Similar to the FDA's fast-track program in the United States, the U.K.'s MHRA Innovation Passport provides Awakn with access to specialist advice from the MHRA and its partners, including the National Institute of Health and Care Excellence (NICE). Throughout the therapeutic development process this has the potential to enable a more efficient, and ultimately a faster route to marketing authorization.

On February 9, 2023, the Company announced it has initiated a feasibility study of MDMA leveraging Catalent's proprietary Zydis® ODT fast dissolve technology. The study is focused on establishing the feasibility of using Catalent's Zydis ODT technology for the formulation and delivery of MDMA. A variety of chemical parameters are presently being evaluated to access preliminary formulations and, if proven to be feasible, a viable production formulation will be developed. The ultimate aims of the study are to optimise the delivery of MDMA, to minimise the amount of drug required to deliver efficacy, minimise variability in absorption, and to increase the overall speed of onset. Due to the faster onset of effects of Zydis ODT technology, there is the possibility to shorten sessions and, through pre-gastric absorption and bypassing of the first-pass metabolism, there is potential to enhance pharmacokinetics.

On February 14, 2023, the Company announced the opening of Awakn Clinics Trondheim and will begin treating clients. This will be the second Awakn clinic operating in Norway with a further two clinics already based in the UK. As a result of the opening of this clinic, the Company is required to issue an additional 100,000 common shares to the former shareholders of Awakn Norway AS.

On February 21, 2023, the Company announced it has signed its first Licensing Partnership agreement in Europe with a healthcare consortium currently operating in stealthmode ("Portuguese Partner"). The agreement will support the Portuguese Partner's strategy to launch a new chain of medical-psychedelic clinics in Portugal, with the first location in Lisbon. Awakn will provide the Portuguese Partner with an exclusive licence for use of its clinical protocols for the treatment of AUD, Anxiety, Depression, Eating Disorders and PTSD in Portugal for a period of 10 years. Awakn will train the Portuguese Partner's clinicians in the delivery of these protocols and will provide ongoing strategic, operational, risk management, and marketing support.

On February 28, 2023, the Company announced it has signed its fourth Licensing Partnership agreement in North America. The agreement is with Ken Starr MD Wellness Group, an addiction treatment facility in California. This is the first Licensing Partnership Awakn has signed with a dedicated addiction treatment provider.

On April 11, 2023, the Company announced that it acquired the 49% of Awakn Bristol Limited that it did not currently own, resulting in 100% ownership of Awakn Bristol Limited and its Bristol Clinic.

On April 11, 2023, the Company announced that it has completed the filing of three Patent Cooperation Treat (PCT) applications for its NCE program, which has resulted in the issuance of an additional 70,000 common shares to Prof. David Nutt pursuant to the Intellectual Property Transfer Agreement with Equasy Enterprises Ltd.

On April 13, 2023, the Dr. Ben Sessa resigned from his role as Head of Psychedelic Medicine at Awakn.

On April 18, 2023, the Company announced that it has signed a Collaboration Agreement with the University of Exeter putting in place a framework for the upcoming Phase III trial for the use of ketamine-assisted therapy to treat Severe AUD. The trial will be n=280, two-armed randomized placebo-controlled trial. It will be delivered across ten NHS sites, and Awakn will contribute approximately GBP800,000 towards the costs of the trial, with the National Institute for Health Care Research and Medical Research Counsel and University of Exeter contributing the balance of the costs.

On April 26, 2023, the Company announced a non-brokered private placement financing for gross proceeds of up to \$3,000,000 through the issuance of up to 6,521,739 units in the capital of the Company (the "Units") at a price of

\$0.46 per Unit (the "Offering"), and that the Company has closed the first tranche of the Offering issuing 2,392,858 Units for gross proceeds of \$1,100,715. Each Unit is comprised of one common share in the capital of the Company and three quarters of one whole Common Share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitles the holder thereof to acquire one Common Share at a price of \$0.63 per Common Share for a period of five years from the date of issuance.

### **Industry Information and Market Trends**

### **Addiction**

There are two broad categories of Addiction that the Company is focused on: (i) substance addiction and (ii) behavioral Addiction. Between 15% and 20%<sup>1</sup> of the of the global adult population suffer from substance addiction, that's between 840 million and 1.1 billion people. Treatment rates are typically low and relapse rates are typically high. For example, with AUD, which affects 5% of the global adult population, only 16% of those suffering with AUD seek treatment and there is a 70% relapse rate within the first 12 months for those that do seek treatment<sup>2</sup>. Up to another 27%<sup>3</sup> of the US adult population are affected by behavioural Addictions.

Despite only treating a minority of those suffering from Addiction and with high relapse rates, the global Addiction treatment industry is currently valued at US\$17.5bn per annum, forecast to increase to US\$31.5bn per annum by 2027<sup>4</sup>.

### Operations

### Research and Development

### Drug and Therapy Research and Development

The Company's goal is to be the global leader in the research of psychedelic therapies and NCE drugs to treat addiction. To achieve this goal, the Company is driving broad research and development activities, in parallel, to reduce both time and cost to market.

### Short term focused IP and development projects:

Project 1 – Phase 3 study in the UK.

The Company has acquired an exclusive license to the Phase II ab Ketamine for reduction of Alcoholic Relapse ("**KARE**") clinical trial, from the University of Exeter, where 86% abstinence over the six month period post treatment. The Company will be delivering the proprietary therapy in its clinics, calling the treatment Awakn Kare.

The National Instituted For Health and Care Research a UK government agency, approved grant funding for the Phase III clinical trial exploring the use of Awakn Kare for the treatment of AUD, which the Company targets to be a pivotal trial. The trial is currently designed to include 280 patients and they will be followed up over the course of six to 12 months. The Company will be working with the University of Exeter and 7 NHS trusts as part of the study. Upon completion of the trial, the Company hopes to seek NICE approval.

*Project* 2 - (S)*-ketamine Oral Thin Film* 

<sup>&</sup>lt;sup>1</sup> Awakn's estimate is based on WHO's report (Percentage of people aged 15 years and older with harmful alcohol use or dependence globally in 2016), North American Foundation for Gambling Addiction Help statistics, and World Cancer Report: Cancer Research for Cancer Prevention <sup>2</sup> Source: "Treatment rates for alcohol use disorders: a systematic review and meta-analysis" by Tesfa Mekonen.

<sup>&</sup>lt;sup>3</sup> Prevalence of the Addictions: A Problem of the Majority or the Minority? Steve Sussman, Nadra Lisha, and Mark Griffiths, 2011

<sup>&</sup>lt;sup>4</sup> Source: Reports and Data (reportsanddata.com) - Drug Addiction Treatment Market.

The Company has signed a twelve-month option agreement to in-license a proprietary (S)-ketamine oral thin film, which has already completed a phase 1 research study. The Company has initiated an investigative study to establish the dissociative effect of the OTF. If the results of tis study are positive, the Company will look to sign a global licensing agreement, and move forward on a phase II b study.

# Medium term focused IP and development projects:

# Project 3 – MDMA on Zydis Technology

The Company has signed a drug development agreement with Catalent for Zydis® Technology (an orally disintegrating tablet) to conduct feasibility studies to improve differentiation of its MDMA program. Zydis is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water and has a dispersion speed of as little as three seconds. The Company is currently conducting a feasibility using Zydis technology.

### Long term focused IP and development projects:

The Company has filed four PCT's related to NCE's, however, the Company has elected to halt its NCE programs until the Company cost of capital is reduced.

# Intellectual Property (IP)

The Company has developed proprietary processes, including its clinical techniques. As not all aspects of the business may be patented, the Company relies on non-disclosure and confidentiality agreements and trade secret protections. In addition to this, the Company has acquired and developed significant amounts of relevant IP.

*Proprietary Research Data:* On March 8, 2021, the Company acquired from Equasy Enterprises, a company established and controlled by Professor David Nutt, five years of proprietary research data to facilitate the identification and development of MDMA and ketamine-like molecules (the "**Nutt Research**"). The data acquired provides significant insights into the basic pharmacological mechanisms of action for MDMA. The Nutt Research has facilitated the identification of several new and innovative molecular targets that will form the basis of both the Company's NCE drug development program and generation of new patents for the Company.

*Ketamine for reduction of Alcoholic Relapse (KARE)*: On March 1, 2021, the Company acquired from the University of Exeter an exclusive licence to use and deliver the KARE psychotherapy intervention, as validated in a Phase II clinical trial led by the University of Exeter (the "**Exeter Licence**"). The KARE clinical research study, led by Professor Celia Morgan (a member of the Clinical Advisory Board of the Company) of the University of Exeter, was a Phase II a/b, four-armed, placebo-controlled trial assessing ketamine combined with the KARE psychotherapy in the treatment for AUD. The study started in 2016, finished in 2020 and included 96 participants and was funded by the Medical Research Council. The primary endpoints of the Phase II trial were percentage days abstinent and relapse at six months, with secondary endpoints including depressive symptoms, craving, and quality of life. The research study showed in the KARE therapy arm, 86% abstinence over the six-month period post treatment, and those in the KARE therapy arm were 2.7 times less likely to relapse than the placebo education group. The therapy manual from KARE has been placed under copyright, and the copyright has been assigned to the Company.

*Patent Filings*: The Company is consistently exploring which aspects of its business may qualify for patentability. The Company will from time to time file provisional patents. The Company currently has filed six different provisional patents, three of which relate specifically to NCE's, and three which relate to other aspects of the Company's operations.

*Trademarks:* The Company has registered or has filed to register, the following name and design of trademark protection under Canada, United States, United Kingdom, the European Union Intellectual Property Office ("**EUIPO**") and the World Intellectual Property Organization ("**WIPO**"). This includes the name Awakn, the Awakn Logo as well as the Awakn "A", produced here:

# Awakn



### **Commercialization**

The Company currently operates four clinics, two in the United Kingdom (London and Bristol), and two in Norway (Oslo and Trondheim). Each clinic offers ketamine-assisted psychotherapy based, initially, on the Exeter Licence (Awakn Kare for AUD) as well as the Company's proprietary protocols, delivered by a team of trained psychiatrists and therapists (the "Awakn Ketamine-Assisted Psychotherapy"). The Company partnered with a leading design agency to design and deliver an evidenced-based client-centered clinic providing a warm, positive, safe environment that better enables people to engage with the therapy, address their trauma as required, and find an opportunity for healing. The leading expert on ketamine-assisted psychotherapy, Professor Celia Morgan who is a member of the Clinical Advisory Board of the Company, supports the Company's activity by introducing evidence-based ketamine-assisted psychotherapy for AUD into the Company's clinics throughout the United Kingdom and Norway.

The Company also has a licensing model that allows the Company to train and enable psychiatrists and therapists to utilize the ketamine-assisted psychotherapy of the Company which is expected to lead to market share growth, drive revenue and widen access and participation in the Company's services to further the agenda of tackling mental illness. The Company's licensing model is focused on the Awakn Kare treatment for AUD. To date the Company has signed five separate licensing agreements, one in Canada, three in the United States and one in Portugal.

Ketamine primarily works as a non-competitive N-methyl D-aspartate receptor antagonist. More recently, ketamine has also been identified as interacting with cholinergic, adrenergic, monoamine and opioid receptors. The literature is strongly supportive of the use of ketamine in accident and emergency departments. Expressing low toxicity, high efficacy and reliable sedation and anaesthesia, ketamine's rapid onset of action, and low interaction with other drugs demonstrates its safety in medical and clinical practice (Kurdi, Theerth and Deva, 2014). In recent years, ketamine has been developed, and used off-license, for psychiatric indications, especially in treatment-resistant depression where it has similarly shown to be safe and effective (Srivastava et al 2015, Murrough et al 2013, Shiroma et al 2020).

There exists a strong evidence base for using ketamine as a purely psychopharmacological agent (with minimal or no psychotherapy) for the management of TRD, (Srivastava et al 2015, Murrough et al 2013, Shiroma et al 2020, Diamond et al 2014), with many clinics around the world, particularly in the United States, and at least one such clinic in the United Kingdom, providing such a service. However, there are fewer clinics internationally, and none in the United Kingdom to date, that combine the drug ketamine with psychotherapy.

In addition to AUD, the Company's clinics provide treatment for a broad range of psychiatric indications with Awakn's Ketamine-Assisted Psychotherapy as clinicians work collaboratively with clients to understand their difficulties, expectations and objectives, to formulate a treatment plan that is tailored to each client. There is an increasing global network of clinicians providing outcome data and treatment protocols for this broader range of psychiatric indications for ketamine-assisted psychotherapies which includes the following psychiatric indications: Depressive Disorders (*Shiroma et al 2020, Schwartz et al 2016, Xu et al 2015, Mandal et al 2019*), Bipolar Disorder (dep phase) (*Grady et al 2017, Ionescu et al 2014*), Anxiety Disorders (*Glue 2017/2018, Rodriguez2013, Bloch2012*), PTSD (*Feder et al 2014, Donoghue 2015*), Substance Use Disorders (*Krupitsky '95,'07, Ezquerra-Romano 2018*) and Eating Disorders (*Scolnick 2020, Mills 1998, Dechant 2020*). Underlying all of these psychiatric indications there are frequently issues of trauma, often going back to childhood maltreatment and abuse, that underpin the chronicity of the patients' mental health problems.

In order to provide a consistent approach to the delivery of psychological therapies for the range of psychiatric indications described above, combined with ketamine, the clinical team of the Company has produced a therapy treatment manual, which is used by clinical staff of the Company across all clinics. The Awakn Ketamine-Assisted Psychotherapy treatment manual draws on psychological theories developed from several existing models of

psychological therapies currently being used, including those combined with other psychedelic-assisted treatment and research protocols.

Awakn's Ketamine-Assisted Psychotherapy is provided off-license. The prescribing physician abides by the general guidelines for using any off-license drug (MHRA guideline online in the UK). The Company uses ketamine in a minimally invasive method of administration, intra-muscularly ("IM"), not intravenously ("IV") and all clients undergoing courses of ketamine treatment receive regular supportive psychotherapy, which provides an extra level of safety and monitoring of response and effects. The Awakn Ketamine-Assisted Psychotherapy protocol is comprised of referral and triage (including review of patient medical notes), face to face initial medical assessment, up to four ketamine-assisted psychotherapy sessions, non-drug integration psychotherapy sessions and a final outcome review session. The Company's clinics offer 11 sessions of psychotherapy, spread over a 9-week course, which include four ketamine-administrations delivered over 6-weeks alongside non-drug therapy sessions, and a final post-course evaluation session on week-9, three weeks after the end of the therapeutic course. Over the therapeutic 6-week course, the ketamine dose will be titrated according to individual response. This will allow the therapeutic relationship to be well established before the patient considers opting for higher doses which facilitates a transformational state with increasing opportunity for dissociative experiences. After the initial 6-week course, patients will be seen for a final follow-up session, 3-weeks later. If clinical judgment suggests value, they may then be offered a repeat of the full course again, the option of a shorter 4-week course, or further single booster sessions of ketamine, with accompanying single sessions of preparation and post-drug psychotherapy at less frequent intervals.

# **Objectives and Milestones**

The following milestones are "forward-looking statements" and as such, there is no guarantee that such milestones will be achieved on the timelines indicated or at all. Forward-looking statements are based on management's current expectations and are subject to a number of risks, uncertainties, and assumptions. See "Forward-Looking Statements" and "Risk Factors".

Milestone <sup>(1)</sup>	Target Date (Calendar Quarter)	Status
Phase II ab KARE: Ketamine for reduction of Alcoholic Relapse, acquired under license from University of Exeter publication in American Journal of Psychiatry	Q4 2021	Completed
Open Awakn Medical Psychedelic-Assisted Psychotherapy Clinic in London, United Kingdom	Q1 2022	Completed
New Chemical Entity drug development: Lead series identified	Q1 2022	Completed
Early feasibility study on Gambling addiction, compulsive sexual behavior, gaming addiction and binge eating disorder	Q2 2022	Completed
Therapeutics Commercialization: Ketamine-Assisted Therapy for Treatment of Alcohol Use Disorder ("KARE") developed and launched into US and Canada	Q3 2022	Completed
Open additional Awakn Medical Psychedelic-Assisted Psychotherapy Clinic in Trondheim, Norway	Q1 2023	Completed
Complete testing of proprietary formulation for S-ketamine to ensure appropriate dissociation effects are achieved	Q2 2023	In Progress
Mechanistic study of Ketamine in Gambling addiction.	Q2 2023	In Progress
Sign exclusive global licensing agreement for a proprietary formulation for (S)- ketamine for Addiction, Anxiety, Eating Disorders and PTSD	Q2 2023	Not started
Ketamine for reduction of Alcoholic Relapse Phase III MHRA regulatory and ethics approval	Q2 2023	In Progress

Milestone <sup>(1)</sup>	Target Date (Calendar Quarter)	Status
Open larger Awakn Medical Psychedelic-Assisted Psychotherapy Clinic in Oslo, Norway	Q2 2023	In Progress
Zydis MDMA feasibility study stage one completed	Q2 2023	In Progress
Complete Zydis MDMA feasibility study	Q3 2023	In Progress
Negotiate and execute global license agreement for Zydis MDMA	Q3 2023	Not Started
Ketamine for reduction of Alcoholic Relapse Phase III first participant, first visit	Q3 2023	Not started
IND submission to FDA for proprietary (S)-ketamine to treat AUD	Q4 2023	Not Started

(1) All milestones related to the Company's New Chemical Entity drug development have been removed as the Company is focusing its capital resources on its Ketamine and Zydis MDMA research programs.

### Specialized Skills and Knowledge

In order to optimize delivery of its expanding development pipeline, the Company has established a Preclinical Advisory Board and a Clinical Advisory Board.

### Preclinical Advisory Board

The members of the Preclinical Advisory Board are Professor David Nutt, Chair, Dr. Shaun McNulty, Professor Stephen Husbands, Professor Harriet de Wit and Professor Kevin Fone. The biographies of each member of the Preclinical Advisory Board are set out below:

### Professor David Nutt, Chair

For Professor Nutt's biography, see section entitled "Directors and Officers" below in this AIF.

### Dr. Shaun McNulty

For Dr. McNulty's biography, see section entitled "Directors and Officers" below in this AIF.

### Professor Stephen Husbands

Professor Husbands is a professor of medicinal chemistry in the Department of Pharmacy and Pharmacology at the University of Bath located in Bath, UK. His research has focused on the development and therapeutic potential of central nervous system targeted ligands, particularly those interacting with multiple receptors. His interests relate to neuropsychological diseases, in particular the development of low abuse liability analgesics and new treatment agents for drug abuse, depression and anxiety. Professor Husbands has more than 120 publications (including book chapters) and his work has been supported by national and international (NIH) funding agencies as well as industry. Professor Husbands' work is highly interdisciplinary, and he collaborates and publishes with researchers around the world.

### Professor Harriet de Wit

Professor de Wit obtained her PhD in Experimental Psychology from Concordia University in Montreal, Canada, in 1981. Since then, she has been associated with the Department of Psychiatry at the University of Chicago, where she is currently Professor and Director of the Human Behavioral Pharmacology Laboratory. In addition to her role as Principal Investigator for several NIH-funded research projects, Professor de Wit serves as Field Editor for the journal Psychopharmacology. She is a consultant to the Food and Drug Administration and serves on scientific advisory boards at other institutions. She has received awards for her research, including the Marian W. Fischman Memorial Lectureship Award in 2009, the European Behavioral Pharmacology Society Distinguished Investigator Award in 2019 and the Research Society on Alcoholism Lifetime Achievement Award in 2020.

### Professor Kevin Fone

Professor Fone is the Professor of Neuroscience at the University of Nottingham. His research interests include improving our understanding of the neurobiological aetiology of common CNS disorders, such as schizophrenia, depression, PTSD and ADHD, and to help develop novel therapeutic treatment strategies for these. His research uses integrated physiology to investigate the functional role of 5-HT and dopamine in the CNS and to evaluate the impact of early-life interventions on brain development and behaviour. The fundamental approach is to concomitantly measure neurotransmitter function, neurochemistry and behaviour in paradigms designed to model CNS disorders. Professor Fone has benefited from extensive funding from Research Councils, EU consortiums, and many pharmaceutical companies from all over the world. He is a Fellow of the British Pharmacological Society, member of the scientific advisory board for the ECNP and has been President for both the International Society for Serotonin Research and the British Association for Psychopharmacology.

# Clinical Advisory Board

The members of the Clinical Advisory Board are Professor David Nutt, Chair, Professor Celia Morgan, Professor Barbara Mason, Dr. Michael Mithoefer and Ann Mithoefer. The biographies of each member of the Clinical Advisory Board are set out below:

### Professor David Nutt

For Professor Nutt's biography, see section entitled "Preclinical Advisory Board" above.

### Professor Celia Morgan

Professor Morgan is a Professor of Psychopharmacology at the University of Exeter in the United Kingdom. Professor Morgan completed her undergraduate degree and Ph.D at University College London (UCL) and completed a scholarship programme at Yale University. After completing her Ph.D, Professor Morgan worked at University of Melbourne as a visiting research fellow, returning to UCL for a fellowship and then Lectureship. She joined University of Exeter as a Senior Lecturer in 2013 and was awarded a Chair in Psychopharmacology position in 2015.

Professor Morgan also holds an Honorary Readership at University College London. Professor Morgan is academic lead for both Exeter Translational Addiction Partnership and Ketamine for Reduction of Alcoholic Relapse (KARE).

### Dr. Michael Mithoefer, M.D.

Dr. Mithoefer began collaborating with MAPS in 2000 on the first U.S. Phase 2 clinical trial of MDMA-assisted psychotherapy. He has since conducted two of the six MAPS-sponsored Phase 2 clinical trials testing MDMA-Assisted Psychotherapy for PTSD, as well a study providing MDMA-assisted sessions for therapists who have completed the MAPS-sponsored MDMA Therapy Training Program, and a pilot study treating couples with MDMA-Assisted Psychotherapy combined with Cognitive-Behavioural Conjoint Therapy.

Dr. Mithoefer is now Senior Medical Director for Medical Affairs, Training and Supervision at MAPS Public Benefit Corporation (MAPS PBC). He is a Grof-certified Holotropic Breathwork Facilitator, is trained in EMDR and Internal Family Systems Therapy and has nearly 30 years of experience treating trauma patients.

### Ann Mithoefer, B.S.N.

Mrs. Mithoefer is a registered nurse focused primarily on training and supervising therapists conducting MAPSsponsored clinical trials, as well as continuing to conduct some MAPS research sessions. Between 2004 and 2018, Mrs. Mithoefer and her husband, Dr. Michael Mithoefer, M.D., completed two of the six MAPS-sponsored Phase II clinical trials testing MDMA-Assisted Psychotherapy for PTSD, as well a study providing MDMA-assisted sessions for therapists who have completed the MAPS Therapist Training, and a pilot study treating couples with MDMA-Assisted Psychotherapy combined with Cognitive-Behavioural Conjoint Therapy. Mrs. Mithoefer is a Grof-certified Holotropic Breathwork Practitioner, is trained in Hakomi Therapy, and has 25 years of experience working with trauma patients, with an emphasis on experiential approaches to psychotherapy.

# Prof. Barbara Mason

Barbara J. Mason, Ph.D. is Director of the Pearson Center for Alcoholism and Addiction Research, Director of the Laboratory of Clinical Psychopharmacology, and Pearson Family Professor in the Department of Molecular Medicine at The Scripps Research Institute, La Jolla, CA. Prof. Mason's work in medication development for the treatment of substance use disorder has been recognized globally.

Prof. Mason conducted the seminal studies identifying nalmefene as having therapeutic potential for alcohol dependence; and also served as overall Principal Investigator for the US 21-center trial of acamprosate (Campral) for the treatment of alcohol dependence which was conducted in support of FDA approval. Prof. Mason has served on the National Advisory Councils of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA). She has served as a guest expert for the U.S. Federal Food and Drug Administration (FDA) and as a reviewer of research grants for NIH and the Medical Research Council (MRC) of the UK.

### **Competitive Conditions**

### Research and Development

The Company's research and development division is focused on researching and developing treatments to treat Addiction. The biotechnology and pharmaceutical industries are competitive and subject to rapid and significant technological change. The Company's competitors would include large, well-established pharmaceutical companies, and academic and research institutions developing therapeutics for Addictions. Many of the Company's competitors have substantially greater technical, human and financial resources than the Company related to conducting preclinical and human clinical trials of product candidates. Competitors also have more experience in scaling up manufacturing operations and obtaining regulatory approvals of products, which may result in competitors obtaining regulatory approval for products more rapidly than the Company.

# Commercialization

The ketamine assisted therapy businesses in the UK is an emerging industry, and there is currently limited competition. The Company is aware of a limited number of clinics in the UK which offer Ketamine as a treatment, of which none of them provide it combined with psychotherapy. The Company also operates clinics in Norway, where throughout the course of the year, the Company has seen increased competition as multiple clinics have opened up in Oslo. The Company has had to adapt to the increased competition accordingly. The Company believes that the strength of its team, its research backed approach for treating AUD from the KARE study will help to serve as an advantage for the Company.

With the Company's core focus on treating Addiction, other Addiction treatment centers would be seen as competition. The Company expects to face increasing competition from new or existing market participants, some of which may have greater financial resources and technical facilities. Increase competition by larger and better financed competitors could materially adversely affect the business, financial condition and results of operations of the Company. This increases the risk that the Company will not be able to access financing when needed or at all.

### **Regulatory Framework**

The Company operates in the UK through its subsidiaries Awakn Bristol, Awakn UK, Awakn London and Awakn Manchester (collectively the "**UK Subsidiaries**"), in Ireland through its subsidiaries Awakn Europe and Awakn Partnerships (collectively the "**Ireland Subsidiaries**") and in Norway through its subsidiary Awakn Norway.

The Company, through the UK Subsidiaries and the Ireland Subsidiaries, carries on its operations in the UK and Ireland in compliance with the regulatory framework described below.

# Regulation of Drugs in the UK

# (a) Controlled drugs

Ketamine is controlled under the misuse of drugs legislation in the UK. It is classified as a Class B drug under the Misuse of Drugs Act 1971 and as a Schedule 2 drug under the Misuse of Drugs Regulations 2001 ("**MDR**"), and it is unlawful to possess, supply, produce, import or export these in the UK except under a controlled drugs licence from the Home Office of Her Majesty's Government of the United Kingdom (the "**Home Office**").

At present there is no national registry in the UK to monitor the use of ketamine in treating mental health.

MDMA is a controlled substances, classified as Schedule 1 substance under the MDR in the UK.

A Home Office licence is required by a healthcare service provider for the production, possession and/or supply of these drugs. These drugs can be used in clinical trials in the UK, subject to a Home Office licence having been obtained.

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (as amended by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020) promote good governance concerning safe management and use of controlled drugs in England and Scotland. With certain exceptions, healthcare providers must appoint a Controlled Drug Accountable Officer ("**CDAO**"). Systems must be put in place to ensure compliance with the Misuse of Drugs legislation, for recording and reporting concerns or untoward incidents about controlled drug use, and to ensure a range of up to date standard operating procedures to support those governance arrangements. A Company is exempt from appointing a CDAO if it falls within one of the exemptions (i.e. it currently has less than 10 employees in the UK). The Company has appointed a CDAO as it continues to expand its operations.

The 2017 Drug Misuse and Dependence: UK Guidelines on Clinical Management (sometimes referred to as the 'Orange Guidelines' or 'Orange Book') must be followed by clinicians in the UK providing drug treatment for people who use or are dependent on drugs. Clinicians in this context include psychiatrists and other workers providing drug treatment, as well as health and social care professionals who provide limited periods of support for the treatment of drug misuse and dependence (such as during hospitalizations).

(b) Regulation of medicines in the UK – licensing

The regulation of medicines in the UK is undertaken by the UK Medicines and Healthcare Products Regulatory Agency ("**MHRA**") in accordance with the UK Human Medicines Regulations 2012.

The marketing authorization process, and marketing authorization licences, which are required to place a medicinal product on the market in the UK, is managed by the MHRA.

Clinical trials for applications for marketing authorization of medicines in the UK are also managed by the MHRA. The MHRA manages eligibility for clinical trials and phases of the trial (including reporting safety issues).

Before a medicine can be placed on the market and promoted in the UK, it must first be granted a licence which is known as a marketing authorization. While no medicine is completely safe, a licence indicates that proper checks regarding its quality, safety and efficacy have been carried out and the benefits of a medicine are believed by the licensing authority (the MHRA in the UK) to outweigh the risks. The licence will include strict parameters as to the conditions (indications) the medicine has been approved to treat. It will also detail as to whether it can only be supplied through an authorized pharmacy, over the counter, or subject to a prescription issued by a healthcare professional registered with the General Medical Counsel ("GMC").

An unlicensed medicine is one that does not have a marketing authorization licence in the UK, and which cannot be promoted on the market in the UK. However, a GMC registered healthcare professional does have freedom to administer such unlicensed products under the guise of a clinical trial, or at its discretion for a specific patient, where it is believed by the clinician that the treatment may offer benefits to the patient which outweigh the risks, and whilst

in the UK it is not an absolute pre-requisite, where there is not an alternative licensed product available to treat that condition.

Ketamine is licensed as an anaesthetic and for analgesia in the UK. It is not a licensed treatment for depression.

In order to use Ketamine to treat depression as an 'off-label' treatment (i.e. outside the licensed indications), a healthcare professional would require a Schedule 2 controlled drugs licence to possess and supply this drug, which would be granted by the Home Office, Drugs Licensing & Compliance Unit.

The Company's clinicians use their prescribing discretion to deliver Ketamine-assisted psychotherapy 'off-label' to treat addiction, depression, anxiety, PTSD and eating disorders (subject to holding a Schedule 2 Home Office licence to possess and supply ketamine). The Company has received both its CQC certification and Schedule 2 controlled drugs license allowing it to operate both its Bristol and London clinics.

MHRA guidance states that although the MHRA does not recommend "off-label" (outside the licensed indications) use of medicinal products, if a healthcare professional believes a UK licensed product can meet the clinical need, even off-label, it should be used instead of an unlicensed product. This is an MHRA recommendation, but it is not a legal requirement under the UK Medicines Act 1968.

At present, a new marketing authorization application for Northern Ireland may either be included with an application for a UK marketing authorization application, or a separate application may be made under the EMA decentralized and mutual recognition procedures as a concerned EU member state. Any marketing authorization applications submitted following the latter procedure will be effective in Northern Ireland only.

# <u>Regulatory oversight – mental health services</u>

Healthcare providers carrying on certain regulated activities in England are required to register with the CQC. Regulated activities are listed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and include treatment of disease, disorder or injury by a healthcare professional (including mental health services). The CQC monitors, inspects and regulates independent doctors and clinics providing mental health services. The Company has received both its CQC certification and Schedule 2 controlled drugs license allowing it to operate both its Bristol and London clinics.

### Corporate Responsibilities

All UK companies have a statutory obligation under the UK Companies Act 2006 to keep certain registers and records.

UK private companies limited by shares must also produce, keep and maintain a separate register of persons with significant control over the company.

Under the UK Companies Act 2006, the directors of a private company limited by shares have seven general duties. These are: (a) to act within their powers; (b) to promote the success of the company; (c) to exercise independent judgment; (d) to exercise reasonable care, skill and diligence; (e) to avoid conflicts of interest; (f) not to accept benefits from third parties; and (g) to declare an interest in a proposed transaction or arrangement. These general duties apply to all directors of the company.

All UK companies are required to file various forms, returns and documents with the Registrar of Companies under a range of provisions in the UK Companies Act 2006. Some of these filing requirements arise on annual basis, while others are event driven. Breach of statutory obligations imposed upon directors could result in criminal sanctions, including a fine, penalty, disqualification or imprisonment.

# Anti Bribery and Corruption

All businesses operating in the UK are subject to the provisions of the Bribery Act 2010. The Act contains four offences: (a) a general offence covering offering, promising or giving a bribe; (b) a general offence covering

requesting, agreeing to receive or accepting a bribe; (c) a distinct offence of bribing a foreign public official to obtain or retain business; and (d) a strict liability offence for commercial organizations where they fail to prevent bribery by those acting on their behalf.

An organization commits an offence if a person associated with it bribes another person for that organization's benefit. An organization has a defence it can show it had "adequate procedures" in place to prevent bribery. "Adequate procedures" are not defined in the Bribery Act, but the Ministry of Justice has published guidance on what adequate procedures might involve. The guidance sets out the following six principles for companies to follow: (a) proportionate procedures; (b) top level commitment; (c) risk assessment; (d) due diligence; (e) communication; and (f) monitoring and review.

The potential consequences of being convicted of a bribery offence include criminal penalties for both individuals and companies. Individuals can be jailed for up to ten years and could also receive an unlimited fine. Organizations can receive unlimited fines. Fines for organizations are likely to be substantial. No guidance has been given yet, but a judgment in the Crown Court in 2010 against a company that had bribed foreign public officials stated that fines for corruption should be in the tens of millions or more.

"Senior officers" can also be convicted of an offence where they are deemed to have given their consent or connivance to giving or receiving a bribe or bribing a foreign public official. It is possible that omitting to act might be regarded as consent or connivance and lead to prosecutions, fines and imprisonment. A director convicted of a bribery offence is also likely to be disqualified from holding a director position for up to 15 years.

# Anti Modern Slavery

The Modern Slavery Act 2015 is aimed at increasing transparency in supply chains. Specifically, large businesses are required to disclose the steps they have taken to ensure their business and supply chains are free from modern slavery (that is, slavery, servitude, forced and compulsory labour and human trafficking). "Commercial organizations" (body corporates or partnerships carrying on any part of their business in the UK) that supply goods or services and have a minimum turnover of £36 million (including turnover of subsidiaries) are required to produce a slavery and human trafficking statement each financial year. This is a statement of the steps taken (if any) to ensure modern slavery is not taking place in its' business or supply chains (this does not mean an organization must guarantee the entire supply chain is slavery free). The statement must be approved by the board, signed by a director and be published on the company website.

The UK government has released statutory guidance providing advice on what should be included in a statement. Although there are no penalties under the Modern Slavery Act for failing to comply with the disclosure requirement (except that the Secretary of State can apply for an injunction to compel compliance), a failure to publish an accurate and robust slavery and human trafficking statement may attract criticism and negative publicity from key stakeholders and others in the community. Tougher legislation in this area is expected to come into force in the medium term.

# Data Protection

The UK left the European Union ("**EU**") on January 31, 2020. The transition period under the terms of the UK-EU withdrawal agreement ended on December 31, 2020 (the "**Transition Period**").

The trade and co-operation *agreement* between the UK and the EU, implemented by the European Union (Future Relationship) Act 2020, addresses the arrangements following the end of the Brexit transition period on December 31, 2020.

This agreement contains a mechanism for data transfers from the EU to the UK which applies for four months from the agreement entering into force, extended by two months unless one of the parties objects, or, if earlier, until there is an adequacy finding for the UK. During this time, personal data transfers from the EU to the UK can continue without additional safeguards provided that the UK's applicable data protection regime continues to apply.

From the end of the Transition Period, the retained EU law version of the General Data Protection Regulation ((*EU*) 2016/679) ("**UK GDPR''**) applies in the UK, along with the *Data Protection Act 2018* ("**DPA 2018''**).

# GDPR Compliance Obligations

All organizations in the UK are subject to the following laws:

- 1. the Data Protection Act 2018,
- 2. the Retained EU law version of the General Data Protection Regulation ((EU) 2016/679) ("UK GDPR"), and
- 3. the GDPR in the context of its extraterritorial reach where the Company processes data relating to EEA data subjects

# (the "Data Protection Legislation").

As currently drafted, the Data Protection Act 2018 and the UK GDPR contain analogous definitions and obligations.

It is essential to inform employees, patients, vendors, research partners, regulators and the courts of the Company's commitment to compliance with Data Protection Legislation. It is also vital that the Company demonstrates that it understands its obligations as a controller of personal data and has in place all measures to achieve compliance. The majority of personal data processed relates to the Company's patients or its employees. The patient data will include "special category" data which carries additional compliance obligations.

The Company will act as a Data Controller in respect of most personal data it processes.

Almost anything done with data counts as *processing*, including collecting, recording, storing, using, analysing, combining, disclosing or deleting it. Processing is defined in Art 4.2 UK GDPR as: 'any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

A *controller* is a person that decides how and why to collect and use the data. The controller must make sure that the processing of such data complies with data protection law. The Company is a controller concerning data of a) its' employees and b) contact details of its supplier's workers, and c) its' patients.

A *processor* is a separate person or organization (not an employee) who processes data on behalf of the controller and in accordance with their instructions. Processors have some direct legal obligations, but these are more limited than the controller's obligations. The obligations when appointing a data processor are as set out in Article 28 of UK GDPR and include amongst other things: (a) having in place a written contract under which the processor agrees only to act on the instruction of the controller; and (b) ensuring adequate security safeguards in place.

The board of directors has a duty to understand its' obligations under the Data Protection Legislation, including the GDPR where it processes EEA data subject data. The UK Information Commissioner has determined that the EEA provides adequate safeguards for the protection of UK data subject data. Therefore, no additional steps are required for UK compliance before transferring personal data to the EEA. The position is not yet the same for EEA data subject data. The European Commission has published a draft adequacy finding for the UK. Should this adequacy finding not be finalised before June 2021, additional measures must be put in place between the Company and any EEA receiving entity.

When it processes EEA data subjects' data in the UK, a company must appoint an EU Data Representative in the location where the majority of its EEA data subjects are based.

Data exported outside of the UK and EEA is subject to additional safeguards, for example, putting in place EU approved standard contractual clauses when exporting data, to ensure such transfers are lawful.

The Data Protection Legislation's new accountability principle requires controllers to be able to demonstrate compliance with the Data Protection Legislation by showing the supervisory authority (the Information Commissioner's Office in the UK, or the relevant regulator in an EEA country where data subject data is processed such as Ireland) and individuals how the controller complies, on an ongoing basis. Elements that a company should be able to demonstrate include internal policies and processes that comply with the requirements of the Data Protection Legislation, the implementation of the policies and processes into the company's activities, effective internal compliance measures and external controls. Failure to comply with the Data Protection Legislation may result in fines of up to  $\notin$ 20 million or 4% of total annual group turnover. Recent fines have been larger where the company involved could not demonstrate that it had a suitable program to manage compliance and demonstrate the accountability principle.

# Intellectual Property

In the UK, intellectual property rights ("IPR") that are (or may be) protected include, in particular:

- confidential information;
- copyright;
- trademarks (both registered and unregistered); and
- patents.

However, other UK IPR may be registered by (or otherwise accrue to) the Company in the course of its business. For example, .uk domain names, UK database rights, UK design rights.

There may be overlap in these IPRs. For example:

• a logo may (in principle) be protected as a registered trademark, an unregistered trademark, a registered design and by copyright;

• a database may be protected by database rights, copyright and the law of confidence.

# Confidential Information

The law of confidence in the UK may be used to restrict the dissemination and unauthorised use of confidential information. To be protected, the information must have a 'necessary quality of confidence'. Broadly speaking, the information must actually be confidential and not merely unavailable to the public in its current form. For example, in respect of information compiled from public sources, thought and effort must have gone into compiling the public information and producing something that deserves protection.

To prevent the actual/threatened unauthorised dissemination/use of the confidential information in the UK, the information must have been disclosed in circumstances importing an obligation of confidence on the recipient. For example, pursuant to a non-disclosure agreement or where the confidential information was shared with an employee in the course of their employment.

The Trade Secrets (Enforcement, etc) Regulations 2018 (SI 2018/597) in the UK provides statutory protection for trade secrets (a subset of confidential information), which are confidential information that:

- are secret;
- are commercially valuable because of their secrecy; and

• have been subject to reasonable steps to keep them secret.

These Regulations allow the owners of trade secrets to restrict the dissemination and unauthorised use of those secrets.

# <u>Copyright</u>

The law relating to copyright in the UK is primarily set out in the Copyright, Designs and Patents Act 1988 ("CDPA").

Copyright law in the UK protects (among others) original artistic and literary works (e.g. photographs, computer programs, text) and audio-visual works. The owner (and, in certain circumstances, licensees) of a copyright work is entitled to prevent others from making unauthorised use of that work (e.g. copying or broadcasting it).

In the UK, copyright protects the expression of an idea, not the idea itself and provides no protection should an idea be independently developed (i.e. where it is not copied).

In the UK, copyright protection for a work will arise automatically, provided that the work qualifies for protection under the CDPA. Qualification is determined by reference to:

- the author's citizenship or jurisdiction of residence; or
- the jurisdiction of first publication/broadcast of the work.

In the UK, the author of a copyright work will be the first owner of that work, provided that – where an employee creates a work in the course of their employment (subject to any agreement to the contrary) – the employer will be the first owner of copyright in the work. Any subsequent assignment of a copyright work must be signed and in writing.

In the UK, the duration of protection will depend on the type of work. In the case of artistic and literary works, the duration of protection is for 70 years from the death of the author.

There is no requirement to register (and there is no process for registration of) copyright in the UK.

# <u>Trademarks</u>

The law in the UK relating to registered trademarks is primarily set out in the Trade Marks Act 1994. Trademarks (and other indicia) may, in principle, also be protected in the UK by the common law of passing-off.

A wide variety of trademarks can, in principle, be registered in the UK. This includes word marks, device marks and combination word and device marks as well as non-traditional trademarks (e.g. sound and colour marks). However, certain types of marks may not be registered. For example, those that are descriptive, non-distinctive, contrary to accepted principles of morality or feature (without consent) the Royal arms.

Applicants must declare that they (or a third party, with their consent) have used the mark in the UK for all of the goods and/or services covered by the application or that they have *bona fide* that it will be so used.

Trademark applications are not subject to *ex officio* examination on relative grounds. In other words, assuming that a trademark is registrable in principle (i.e. is not descriptive etc.) – unless a third party opposes an application – the mark will normally be registered.

Once registered, a trademark must be renewed every 10 years and may be renewed indefinitely.

The owner of a registered trademark (and, in certain circumstances, licensees) is entitled to prevent others from making unauthorised use of:

• an identical mark in relation to goods/services identical to those for which the owner's mark is registered;

- an identical/similar mark in relation to goods/services identical/similar to those for which the owner's mark is registered, where this would result in a likelihood of confusion on the part of the public;
- an identical/similar mark, where the owner's trademark has a reputation in the UK and the use of the mark is without due cause and takes unfair advantage of (or is detrimental to) the distinctive character or the repute of the owner's trademark.

There is no requirement in the UK for the proprietor to file a declaration of use of a registered mark. However, to the extent that a registered UK trademark has not been used within the five years following registration – unless there are proper reasons for the lack of use – the mark may be revoked on application.

# **Patents**

The law in the UK relating to patents is primarily set out in the Patents Act 1977.

An invention may be protected (on application for registration) by patent if it:

- is new;
- involves an inventive step;
- is capable of industrial application; and
- is not specifically excluded from protection as a patent.

The owner of an invention is the only person entitled to prosecute an application to patent that invention. The inventor is usually the first owner of an invention, provided that (subject to any agreement to the contrary) where an employee develops an invention in the course of:

- their normal duties or specifically assigned duties (falling outside of their normal duties); or
- the duties of the employee and the employee had a special obligation to further the employer's interests.

Once registered, from the fourth anniversary of filing, a patent must be renewed annually. Subject to renewal, patents have a duration of 20 years from filing of the fuller application. (Where the patent protects the active ingredients used in a pharmaceutical product, a Supplementary Protection Certificates may be obtained which provide up to five years' further protection.)

A patent allows the owner to restrain any unauthorised use of the invention covered by the patent.

# Licensing IPR in the UK

While there are common law and statutory restrictions on commercial parties' ability to freely contract (e.g. liability for death and personal injury caused by negligence cannot be excluded or restricted) and there are regulatory restrictions that will apply to the parties' activities (and their ability to freely contract) generally (e.g. the use and sale of controlled substances, the practising of medicine), in respect of IPR licensing specifically, there are only limited restrictions in the UK on parties' freedom to contract. The primary consideration would be whether any aspect of an IPR licence might have an anti-competitive aim/effect (i.e. contrary to the UK's Competition Act 1998).

Otherwise, the primary UK-specific licensing consideration would be the terms on which a licensee was entitled to sue for infringement (or not); in respect of certain IPR, licensees are granted the right (unless excluded in the licence) under statute to sue in respect of infringements of those IPR.

To be effective, licences of certain IPR must be signed and in writing. Licences of registered IPR may be recorded with the UK Intellectual Property Office.

Following the Axon Acquisition, the Company expanded its operations in Norway. The Company, through Awakn Norway, carries on its operations in Norway in compliance with the regulatory framework described below.

### Regulation of Medicines in Norway

### Overview of Applicable Legislation and Relevant Authorities

In Norway, the legislation on medicinal products is set out in various acts and regulations, *inter alia*, the Medicines Act (*Nw: Legemiddelloven*, LOV-1992-12-04-132), the Medicines Regulation (*Nw: Legemiddelforskriften*, FOR-2009-12-18-1839), and the Narcotics Regulation (*Nw: Narkotikaforskriften*, FOR-2013-02-14-199). The regulation of medicines is harmonized with relevant EU regulations.

The Norwegian Medicines Agency ("**NoMa**"), an agency under the Ministry of Health and Care Services, is responsible for ensuring the efficacy, quality, and safety of medicines. NoMa's responsibilities include the authorization of the manufacturing, import, sale, and distribution of medicines, in addition to authorization of the use of medicines that do not have a marketing authorization.

### Manufacturing, Import, Sales, etc. of Medicines

As for the manufacturing of medicines, a manufacturer permit must be obtained from NoMa in order to manufacture medicines, cf. Section 2-1 of the Manufacture and Importation of Medicines Regulation (Nw: Forskrift om tilvirkning og import av legemidler, FOR-2004-11-02-1441) (the "**Regulation**"). The Regulation sets out the applicable obligations that come into force when manufacturing medicines. Some overall obligations are set out in Section 2-8 of the Regulation, under which the manufacturer must ensure that all manufacturing is carried out in accordance with guidelines for good manufacturing practice and guidelines for good distribution practice and the requirements set out in the manufacturer's permit. A permit is also required in order to import medicines, cf. chapter 3 of the Regulation.

As for the sale of medicines, different rules apply to pharmacies, wholesalers, or other vendors. The applicable legislation also differentiates between prescription-free (over-the-counter) medicines and prescription medicines.

# Marketing Authorization

Pursuant to Section 8 of the Medicines Act, for medicines that are manufactured industrially or using an industrial process to be marketed in Norway, the medicine must have a marketing authorization. Such authorization is granted on the basis of an assessment of the preparation's quality, safety, and efficacy, meaning that new medicinal products must undergo an evaluation based on these criteria prior to being placed on the market. Before a marketing authorization is granted, the product's name, prescription status, product description, labeling, packaging, package insert, and other equipment must be approved. Provisions on the further requirements for obtaining marketing authorization, exemptions from the requirement, the application procedure, etc. are set out in the Medicines Regulation.

NoMA is responsible for granting marketing authorizations.

# Off-label Use of Medicines

If a medicine has not been granted marketing authorization for a certain use, it may still be used for that purpose "offlabel". Off-label use of medicines means that the medicine is used to treat a medical condition for which it has not been granted marketing authorization, i.e. outside the authorized indication. There is no ban on off-label use of medicines under Norwegian law. The medical practitioner has the freedom to decide whether a medicine may be prescribed for off-label use provided that the off-label use of the medicine is considered to be medically justifiable.

## The use of Ketamine as Medicine

Ketamine is considered a medicine in Norway and is classified as an A-preparation (prescription group A), which covers highly addictive medicines with a risk of abuse. Although many medicines classified as A-preparations are also classified as narcotics pursuant to the Narcotics Regulation, this does not apply to ketamine.

Ketamine has been granted marketing authorization in Norway as an anesthetic under the trade names Ketalar, Ketamin Abcur, and Ketanest. The marketing authorization covers the use as an anesthetic in diagnostic or surgical procedures of a short-term nature, as an initial anesthetic before the administration of other anesthetics, and as a supplement to other anesthetics.

However, other ketamine products may be used off-label for the treatment of depressions as described in section entitled "*Off-label Use of Medicines*" above. Such use of ketamine does take place in Norway. In addition to the use of ketamine for the treatment of depression in the private health sector, since the end of 2020 public hospitals in Norway have started using ketamine off-label for the treatment of depressions.

As Ketamine is considered a medicine in Norway, the general criteria for manufacturing, importation and sale of medicines as described in section entitled "*Manufacturing, Import, Sales, etc. of Medicines*" above applies.

# The Provision of Health Services

Healthcare providers must follow the Health Personnel Act when providing medical assistance. Pursuant to Section 48, 48a, and 49 of the Health Personnel Act, health personnel who are to practice their profession in Norway must be registered and hold a license or authorization. Further, for health services, the Act on Specialist Health Services governs the provision of specialist health services that are provided either publicly or privately.

A general requirement for the provision of health services is set out under Section 2-2 of the Norwegian Act on Specialist Health Services and Section 4 of the Health Personnel Act, under which there are requirements implying that health services must be sound. This requirement must be taken into account for the provision of any health service including off-label use of medicines. The assessment of whether a practice is sound must be made based on the individual situation and alternative course of action the health personnel has. The standard is based on what can be expected on the basis of qualifications, but must also be assessed in the light of the nature of the work and the situation in general.

# **Operation of Awakn Clinics**

Each country that the Company operates in has different regulatory bodies for its medical professionals. Below outlines a table of the applicable laws and regulatory bodies:

Country	Medical Professional	Governing Law	Regulatory bodies
United Kingdom	Doctors	Health Care and Associated Professions (Miscellaneous Amendments) Order 2008	General Medical Council
	Practitioner psychologists	Health Care and Associated Professions (Miscellaneous Amendments) Order 2008	Health and Care Professions Council
	Nurses	The Nursing and Midwifery Council Rules	Nursing and Midwifery Council (NMC)

		2004	
	CBT Therapists	Health Care and Associated Professions (Miscellaneous Amendments) Order 2008	British Association of Behavioural and Cognitive Psychotherapies
	Psychotherapists	Health Care and Associated Professions (Miscellaneous Amendments) Order 2008	Health and Care Professions Council
Norway	Medical Doctors	Lov om helsepersonell m.v. (helsepersonelloven) LOV-1999-07-02-64	Helsedirektoratet
	Clinical Psychologists	Lov om helsepersonell m.v. (helsepersonelloven) LOV-1999-07-02-64	Helsedirektoratet
	Nurses	Lov om helsepersonell m.v. (helsepersonelloven) LOV-1999-07-02-64	Helsedirektoratet

# **Regulatory and Clinical Research Activities**

The Company intends to undertake all regulatory and clinical research activities guided and supported by expert regulatory consultants, provided by contract research organizations possessing extensive experience of current regulatory guidelines, policies and regulations. Clinical trials will only be initiated post clearance by the appropriate regulatory body (MHRA for the United Kingdom, EMA for the European Union and the FDA for the United States) to do so. All appropriate local and national ethical clearance will be obtained before patients are recruited and trials begin.

The Company's strategy will be to sequentially progress from Phase 1 clinical verification of safety and tolerability for a particular compound/treatment paradigm towards efficacy and finally marketing authorization enabling studies. A summary of the stages are as follows:

**Pre-Clinical** - Before testing any medicinal product in humans, the product candidate undergoes thorough testing which includes lab-based evaluations of drug chemistry, formulation and stability, as well as lab-based in vitro (cell-based) testing and in vivo (in animal) studies to assess biological activity and safety to establish the rationale for safe therapeutic use. The nonclinical studies should be conducted in accordance with applicable laws and regulations, including the Good Laboratory Practice requirements. Results obtained from the nonclinical studies, in addition to GMP manufacture and analytical data, are collectively submitted as a data package to the relevant jurisdiction's regulatory body in order to obtain approval for progressing the drug candidate in clinical trials.

**Clinical** - The clinical stage development of a therapeutic candidate involves the progression through three sequential (occasionally overlapping) clinical phases to evaluate its safety, tolerability and efficacy in healthy subjects and patients for target clinical indications in order to support new drug applications for marketing approval within the targeted jurisdiction. Each clinical phase requires the administration of the therapeutic candidate in humans participating under informed consent (healthy volunteers and/or patients) in accordance with Good Clinical Practice ("**GCP**") requirements and under the supervision of qualified investigators who are typically physicians not under the control of the trial sponsor. Each clinical trial is conducted under a standardized protocol which details the trial objectives, subject selection criteria, study procedures, processes and parameters to monitor the trial safety and additional core procedures. Protocols are submitted to, and must be approved by, the appropriate regulatory bodies.

In addition, the trial is reviewed by an institutional review board (an "**IRB**") and a research ethics committee ("**REC**") who serve to ensure the trial is in the best interest of the trial subjects by ensuring the risks to participating individuals are minimized and reasonable as compared to the anticipated benefits. Each clinical trial may also require reporting information about the results from the trial to a public registry within the relevant jurisdiction. The sponsor is responsible for ensuring that registry data are updated in a timely manner, depending on the jurisdiction, with new information on: safety and, where feasible, efficacy reports; reasons for stopping a trial early; trial results in summary format.

**Phase I** - Phase I studies typically involve the first administration of the investigational product into healthy human volunteers or patients with the target disease. These studies are designed to test the safety, absorption, distribution, metabolism, excretion as well as tolerance of different doses of the investigational product in a relatively small number of subjects. They often also evaluate the pharmacokinetic effects of the test substance.

**Phase II** - Phase II trials are carried out on a limited patient population with the target disease. In Phase II, the objective of the trials is to continue to gather information on the safety and tolerability and side effect profile of the drug and to determine the drug's potential effectiveness to treat the target disease as well as determine optimal dosages and administration schedule. Phase IIa studies are typically conducted across a small number of clinical trial sites or centers (1-4 typically depending upon the number of subjects in the study) and often within one country, whereas Phase IIb studies are typically conducted across multiple clinical trial sites or centers and in a number of different countries to collect sufficient data to enable the product to progress to Phase III studies and subsequent marketing.

**Phase III** - Phase III clinical trials typically involve administering the investigational product to a larger patient population in order to assess treatment efficacy and additional safety of the selected dose(s) and dose regimen. These studies are typically multi-center and multi-country and are intended to assess if the overall risk/benefit ratio is sufficient for market approval of the product.

**Phase IV** - Post-approval studies, or Phase IV clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the applicable regulatory authority as a condition of approval.

# Employees

As of the date of this AIF, the Company has 44 employees, including contractors and part-time employees of affiliates, distributed among the following departments:

Department	Number
Executive	5
Finance	3
Clinical / Partnerships	31
Research	3
Sales and marketing	2

#### **RISK FACTORS**

## **Risks Related to the Business of the Company**

#### Risks Relating to Operations in the United Kingdom

It is unlawful to possess, supply, produce, import or export ketamine in the UK except under a controlled drugs licence from the Home Office of Her Majesty's Government of the United Kingdom (the "**Home Office**"). Failure to obtain or maintain the necessary licences for any of its clinics, or non-compliance with any such licences issued to the Company, could adversely affect the Company's business in the UK.

A Home Office licence is required by a healthcare service provider for the production, possession and/or supply of MDMA because it is deemed to be a controlled drug. MDMA can be used in clinical trials in the UK, although a

controlled drugs licence is still required to use them in clinical trials. Failure to obtain the necessary licences, or noncompliance with any such licences issued to the Company, could adversely affect the Company's business in the UK.

Healthcare providers carrying on certain regulated activities in England are required to register with the CQC. Regulated activities are listed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and include treatment of disease, disorder or injury by a healthcare professional (including mental health services). The CQC monitors, inspects and regulates independent doctors and clinics providing mental health services. The Company has received its CQC licenses for both Awakn Bristol Ltd. and Awakn London Ltd., and will continue to apply for other clinics as required. Failure to obtain the necessary CQC registration, or non-compliance with any CQC registration granted, could adversely affect the Company's business in the UK.

Manufacturers of drugs sold in the UK must have in place quality procedures which comply with Directive 2003/94/EC. This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use. The GMP Guidelines (Volume 4 of the Rules Governing Medicinal Products in the European Union, EU Guidelines for Good Manufacturing Process for Medicinal Products for Human and Veterinary Use, Chapter 7 (Outsourced Activities)) must also be adhered to. Although the UK left the European Union on January 31, 2020, and the Brexit transition period expired on December 31, 2020, Directive 2003/94/EC continues to apply in the UK for the time being (and will apply until the UK implements its own UK laws). Additionally, individuals or companies that procure, hold, sell or supply medicinal products for human use to anyone other than members of the public (i.e. the patient) in the UK must have a wholesale dealer licence. Individual patients must consent to taking drugs as part of their therapy or treatment. Patient consent must be obtained before participation in clinical trials can proceed in the UK, and, in accordance with UK data protection laws, patients must be told how their data will be stored and used, and for what purposes it will be used. Any non-compliance with any of the above referenced rules and regulations, or any other rules or regulations applicable to the Company (see *Regulatory Framework in the United Kingdom*) could adversely affect the Company's business in the UK.

In order to conduct clinical trials in the UK, the trial protocol must be reviewed and approved by a Research Ethics Committee. All clinical trials of medicines must also be authorized by the Medicines and Healthcare Products Regulatory Agency (MHRA). The ethics approvals will need to be submitted to the MHRA when applying for marketing authorizations (namely a licence granted by the MHRA to market and promote a medicine in the UK). Failure to obtain any such approvals or authorizations could have an adverse effect on the Company's business in the UK.

Failure to comply with the Data Protection Legislation in the UK may result in fines of up to €20 million or 4% of total annual group turnover. Recent fines have been larger where the company involved could not demonstrate that it had a suitable program to manage compliance and demonstrate the accountability principle. The UK Information Commissioner has wide ranging powers which include the ability to prevent the Company using patent data until it has a suitable compliance regime in place. In addition, an organization commits an offence under the Bribery Act 2010 if a person associated with it bribes another person for that organization's benefit. Individuals can be imprisoned and could also receive an unlimited fine. Organizations can also receive unlimited fines. "Senior officers" can also be convicted of an offence where they are deemed to have given their consent or connivance to giving or receiving a bribe or bribing a foreign public official. It is possible that omitting to act might be regarded as consent or connivance and lead to prosecutions, fines and imprisonment. A director convicted of a bribery offence is also likely to be disqualified from holding a director position for up to 15 years. Any non-compliance with such legislation could have an adverse impact on the Company's business.

# Early stage of NCE Prospects Development may not Succeed

Given the early stage of the Company's product development, the Company cannot make any assurances that the Company's research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, the Company, alone or with others, must successfully develop, gain regulatory approval, and market the Company's future products. Awakn currently has no products that have been approved by the MHRA in the United Kingdom, FDA in the United States or any similar regulatory authority. To obtain regulatory approvals for the Company's product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the product candidates are safe for human use and that they demonstrate efficacy.

Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company or its collaborators to abandon commitments to that program. Positive results of early preclinical research may not be indicative of the results that will be obtained in later stages of preclinical or clinical research. Similarly, positive results from early-stage clinical trials may not be indicative of favourable outcomes in later-stage clinical trials. The Company can make no assurance that any future studies, if undertaken, will yield favourable results.

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

The Company cannot make any assurances that any future studies, if undertaken, will yield favorable results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and the Company cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain MHRA, FDA or other regulatory agency approval.

# Reliance on Third Parties to Plan, Conduct and Monitor Preclinical Studies and Clinical Trials

The Company relies and will continue to rely on third parties to conduct a significant portion of the Company's preclinical and clinical development activities. Preclinical activities include in vivo studies providing access to specific disease models, pharmacology and toxicology studies and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in the Company's relationship with third parties, or if they are unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs will face delays. Further, if any of these third parties fails to perform as the Company's testing could be delayed, cancelled or rendered ineffective.

# Failure to Demonstrate Safety and Efficacy Could Cause Additional Costs and/or Delays

Before obtaining marketing approval from regulatory authorities for the sale of the Company's product candidates, the Company must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. The Company does not know whether the clinical trials it conducts will demonstrate adequate efficacy and safety to result in regulatory approval to market any of the Company's product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of the Company's product candidates under development will successfully gain market approval from the FDA, MHRA or other regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

# Delays in Clinical Testing, will Result in Delays in Commercializing Product Candidates

The Company cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs will increase if the Company experiences delays in clinical testing. Significant clinical trial delays could shorten any periods during which the Company may have the exclusive right to commercialize its product candidates or allow the Company's competitors to bring products to market before it is able to, which would impair the Company's ability to successfully commercialize its product candidates and may harm the Company's financial condition, results of operations and prospects. The commencement and completion of clinical trials for the Company's products may be delayed for a number of reasons, including delays related, but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing the clinical trial on hold;
- patients failing to enroll or remain in the Company's trials at the rate the Company expects;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of the Company's contract manufactures to comply with requirements;
- any changes to the Company's manufacturing process that may be necessary or desired;
- delays or failure to obtain clinical supply from contract manufacturers of the Company's products necessary to conduct clinical trials;
- product candidates demonstrating a lack of safety or efficacy during clinical trials;
- patients choosing an alternative treatment for the indications for which the Company is developing any of its product candidates or participating in competing 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 the Company's clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of the Company's contract research organizations to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by review boards, regulatory authorities, or ethics committees finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more review boards or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

The Company's product development costs will increase if the Company experiences delays in testing or approval or if the Company needs to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and the Company may need to amend study protocols to reflect these changes. Amendments may require the Company to resubmit its study protocols to regulatory authorities, review boards or ethics committees for re-examination, which may impact the cost, timing or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on the Company's business, financial condition and prospects.

# Difficulty Enrolling Patients in Clinical Trials May Result in the Completion of the Trials Bing Delayed or Cancelled

As the Company's product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, the Company will need to enroll an increasing number of patients that meet its eligibility criteria. There is significant competition for recruiting patients in clinical trials, and the Company may be unable to enroll the patients the Company needs to complete clinical trials on a timely basis or at all. The factors that affect the Company's ability to enroll patients is largely uncontrollable and include, but are not limited to, the following:

• size and nature of the patient population;

- eligibility and exclusion criteria for the trial;
- design of the study protocol;
- competition with other companies for clinical sites or patients;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians; and
- the number, availability, location and accessibility of clinical trial sites.

## Regulatory Approval Processes are Lengthy, Expensive and Inherently Unpredictable

The Company's development and commercialization activities and product candidates are significantly regulated by a number of governmental entities, including the MHRA, FDA and comparable authorities in other countries. Regulatory approvals are required prior to each clinical trial and the Company may fail to obtain the necessary approvals to commence or continue clinical testing. The Company must comply with regulations concerning the manufacture, testing, safety, effectiveness, labeling, documentation, advertising, and sale of products and product candidates and ultimately must obtain regulatory approval before the Company can commercialize a product candidate. The time required to obtain approval by such regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials. Any analysis of data from clinical activities the Company performs is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Even if the Company believes results from its clinical trials are favorable to support the marketing of the Company's product candidates, the MHRA, FDA or other regulatory authorities may disagree. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The Company has not obtained regulatory approval for any product candidate and it is possible that none of the Company's existing product candidates will ever obtain regulatory approval.

The Company could fail to receive regulatory approval for its product candidates for many reasons, including, but not limited to:

- disagreement with the design or implementation of the Company's 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 the Company's interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of the Company's product candidates to support the submission and filing of a biologic license application or other submission to obtain regulatory approval;
- deficiencies in the manufacturing processes or the failure of facilities of contract manufacturers with which the Company contracts for clinical and commercial supplies to pass a pre-approval inspection; or
- changes in the approval policies or regulations that render the Company's preclinical and clinical data insufficient for approval.

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

#### Competition from other Biotechnology and Pharmaceutical Companies

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The Company's competitors include large, well-established pharmaceutical companies, biotechnology companies and academic and research institutions developing therapeutics for the similar indications

the Company is targeting as well as competitors with existing marketed therapies. Many other companies are developing or commercializing therapies to treat the same diseases or indications for which the Company's product candidates may be useful. Some competitors use therapeutic approaches that may compete directly with the Company's product candidates.

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

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

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

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

# Negative Results from Clinical Trials

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's product candidates, or the therapeutic areas in which its product candidates compete, could adversely affect the Company's share price and its ability to finance future development of the Company's product candidates and the Company's business and financial results could be materially and adversely affected.

# Reliance on Third Parties Requires Sharing of Trade Secrets

The Company relies on third parties to develop its products and as a result, must share trade secrets with them. The Company seeks to protect its proprietary data and technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of the Company's collaborators, advisors, employees and consultants to publish data potentially relating to the Company's trade secrets. Some of its academic collaborators have rights to publish data, provided that the Company is notified in advance and may delay publication for a specified time in order to secure the Company's intellectual property rights arising from the collaboration. In

other cases, publication rights are controlled exclusively by the Company, although in some cases the Company may share these rights with other parties. The Company may also conduct joint research and development programs which may require it to share trade secrets under the terms of research and development collaboration or similar agreements. Despite the Company's efforts to protect its trade secrets, the Company's competitors may discover its trade secrets, either through breach of these agreements, independent development or publication of information. A competitor's discovery of the Company's trade secrets may impair its competitive position and could have a material adverse effect on its business and financial condition.

# Third Party Licenses May be Required to Manufacture Key Products

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

## COVID-19

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2. Since December 31, 2019, the outbreak of COVID-19 has resulted in governments worldwide, including United Kingdom, the European Union, Canada and the United States, enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally, resulting in an economic slowdown. Such events may result in a period of business disruption, and in reduced operations, any of which could have a material adverse impact on the Company's profitability, results of operations, financial condition and the trading price of the Common Shares. Governments and central banks have reacted to the COVID-19 pandemic with significant monetary and fiscal interventions designed to stabilize economic conditions. The duration and impact of the COVID-19 pandemic is unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company.

To date, a number of businesses have suspended or scaled back their operations and development as cases of COVID-19 have been confirmed, for precautionary purposes or as governments have declared a state of emergency or taken other actions. If the operation or development of one or more of the Company's clinics is suspended or scaled back, or if its supply chains are disrupted, it may have a material adverse impact on the Company's profitability, results of operations, financial condition and the trading price of the Company's securities. To the extent that the Company's management or other personnel are unavailable to work due to the COVID-19 pandemic, whether due to illness, government action or otherwise, it may have a material adverse impact on the Company's profitability, results of operations, financial condition and the trading price of the Common Shares. The breadth of the impact of the COVID-19 pandemic on investors, businesses, the global economy and financial and commodity markets may also have a material adverse impact on the Company's profitability, results of operations, financial conditions and the trading price of the common Shares.

#### Non-Compliance with Laws

Non-compliance with federal, provincial, or state laws and regulations, or the expansion of current, or the enactment of new, laws or regulations, could adversely affect the Company's business. The activities of the clinics operated by the Company and the medical personnel operating such clinics are subject to regulation by governmental authorities, and the Company's business objectives are contingent, in part, upon its and its personnel's compliance with regulatory requirements enacted by these governmental authorities, and obtaining all regulatory approvals, where necessary, for the carrying on of business at the clinics operated by the Company. Any delays in obtaining, failure to obtain, or violations of regulatory approvals and requirements would significantly delay the development of markets and products and could have a material adverse effect on the business, results of operations and financial condition of the Company.

# **Risks Related to Prescribing Medication**

Governmental medical boards or other regulatory bodies could take disciplinary action against the Company's physicians for excessive psychedelic prescriptions. Physician prescription patterns may be tracked and may be used to impose disciplinary action on physicians who prescribe psychedelics at a high rate. If any of the Company's physicians are deemed to be prescribing psychedelics excessively, such physicians could face disciplinary action, including, revocation of the physician's license. Any disciplinary action or license revocation of physicians who work at a clinic operated by the Company could result in such clinic not having sufficient physicians to address patient needs and could adversely affect the Resulting's business.

# Risks Inherent in the Nature of the Health Clinic Industry

Changes in operating costs (including costs for maintenance, insurance), inability to obtain permits required to conduct the Company's business, changes in health care laws and governmental regulations, and various other factors may significantly impact the ability of the Company to generate revenues. Certain significant expenditures, including legal fees, borrowing costs, maintenance costs, insurance costs and related charges, must be made to operate the clinics operated by the Company, regardless of whether the Company is generating revenue.

# Unfavourable Publicity or Consumer Perception

The success of the psychedelic therapy industry may be significantly influenced by the public's perception of psychedelic medicinal applications. Psychedelic therapy is a controversial topic, and there is no guarantee that future scientific research, publicity, regulations, medical opinion, and public opinion relating to psychedelic therapy will be favourable. The psychedelic therapy industry is an early-stage business that is constantly evolving, with no guarantee of viability. The market for psychedelic therapy is uncertain, and any adverse or negative publicity, scientific research, limiting regulations, medical opinion relating to the consumption of psychedelic therapy may have a material adverse effect on the Company's operational results, consumer base and financial results.

# Social Media

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

# **Patient Acquisitions**

The Company's success will depend, in part, on its ability to attract and retain patients. There are many factors which could impact the Company's ability to attract and retain patients, including the successful implementation of the Company's patient-acquisition plans and the continued growth in the aggregate number of patients selecting psychedelic therapy as a treatment option. The Company's failure to acquire and retain patients as clients would have a material adverse effect on the Company's business, operating results and financial condition.

# **Reliance on Personnel**

The Company's success depends to a significant extent on its ability to identify, attract, hire, train and retain qualified personnel. Competition for such personnel may be intense and there can be no assurance that the Company will be successful in identifying, attracting, hiring, training and retaining such personnel in the future. If the Company is unable to identify, attract, hire, train and retain qualified personnel in the future, such inability could have a material adverse effect on its business, operating results and financial condition.

### Development Risks

Future development of the Company's business may not yield expected returns and may strain management resources. Development of the Company's revenue streams is subject to a number of risks, including construction delays, cost overruns, financing risks, cancellation of key service contracts, and changes in government regulations. Overall costs may significantly exceed the costs that were estimated when the project was originally undertaken, which could result in reduced returns, or even losses, from such investments.

## Company may not Achieve its Milestones According to Schedule

From time to time, the Company may announce the timing of certain events that it expects to occur, such as the anticipated timing of results from its clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials or any other event having the effect of delaying the publicly announced timeline. The Company undertakes no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on the Company's business plan, financial condition or operating results and the trading price of Common Shares.

# Substantial Risk of Regulatory or Political Change

The success of the business strategy of the Company depends on the legality of the use of psychedelics for the treatment of mental health conditions and the acceptance of such use in the medical community. The political environment surrounding the psychedelics industry in general can be volatile. As of the date of this AIF, the United Kingdom permits the use of ketamine or a derivative thereof as a treatment for certain mental health conditions; however, the risk remains that a shift in the regulatory or political realm could occur and have a drastic impact on the use of psychedelics as a whole, adversely impacting the Company's ability to successfully operate or grow its business.

#### Government Regulations, Permits and Licenses

The Company's operations may be subject to governmental laws or regulations promulgated by various legislatures or governmental agencies from time to time. A breach of such legislation may result in the imposition of fines and penalties. The cost of compliance with changes in governmental regulations has the potential to reduce the profitability of operations. The Company intends to fully comply with all governmental laws and regulations. The physicians that recommend psychedelic therapy to the Company's patients will be subject to various laws in the United Kingdom. If any permits are required for the Company's operations and activities in the future, there can be no assurance that such permits will be obtainable on reasonable terms or on a timely basis, or that applicable laws and regulations will not have an adverse effect on the Company's business.

The current and future operations of the Company are and will be governed by laws and regulations governing the health care industry, labour standards, occupational health and safety, land use, environmental protection, and other matters. Amendments to current laws, regulations and permits governing operations and activities of health clinics, or more stringent implementation thereof, could have a material adverse impact on the Company and cause increases in capital expenditures or costs, or reduction in levels of its medical services.

#### Non-Referrals

Physicians may not refer patients to the clinics operated by the Company. In addition, as the market grows, and general practitioners become more comfortable and knowledgeable about the psychedelic therapy industry and products available, they may choose to write prescriptions directly for their own patients rather than refer them to an outside clinic.

## Difficult to Forecast

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

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the clinics operated by the Company, could adversely affect the Company's ability to finance future developments or the price of the Common Shares, and the Company's business and financial results could be materially and adversely affected.

## Cyber-Attacks

The Company's operations will depend, in part, on how well it will protect its information technology systems, networks, equipment and software from damages from a number of threats. Events such as cable cuts, power loss, hacking, computer viruses and theft could result in information system failures, delays and/or increase in capital expenses for the Company. While it is expected that the Company will implement protective measures to reduce the risk of and detect cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly; the development of the Company's business and operating results may be hindered by applicable restrictions on sales and marketing activities imposed by regulatory bodies.

## Competitive Risks

The psychedelic therapy business in the United Kingdom is an emerging industry with high levels of competition. The Company's current business plan is the establishment of a chain of Ketamine-Enhanced Psychotherapy, psychedelic-enhanced psychotherapy and psychedelic-integration psychotherapy clinics in the United Kingdom and the European Union. The Company expects that, due to the urgent need for new and innovative treatments for mental health conditions and the evidence-based studies showing the impact of psychedelics as a treatment for mental health conditions, psychedelics as a treatment for these conditions will become more accepted in the medical community. As such, the Company expects to compete with other similar businesses as well as with individual medical professionals who undertake the prescribing and supervising of psychedelics to their patients. While the Company was an early entrant to the psychedelic-enhanced psychotherapy market, other market participants have emerged. The Company expects to face intense competition from new or existing market participants, some of which may have greater financial resources. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Company.

#### Litigation

The Company may become party to litigation from time to time in the ordinary course of business, including a medical malpractice claim, or a claim based in related legal theories of negligence or vicarious liability among others if a physician at one of the clinics operated by the Company causes injury, which could adversely affect the Company's business. Should any litigation in which the Company becomes involved be determined against the Company, such a decision could adversely affect the Company's ability to continue operating and the market price for the Common Shares. Even if the Company is involved in litigation and wins, litigation can redirect significant resources. Litigation may also create a negative perception of the Company's business.

#### Insurance Coverage

The Company believes that the existing insurance coverage addresses all material risks to which the Company will be exposed and is adequate and customary in the current state of operations, however such insurance is subject to coverage limits and exclusions and may not be available for the risks and hazards to which the Company is exposed.

Moreover, there can be no guarantee that the Company will be able to obtain adequate insurance coverage in the future or obtain or maintain liability insurance on acceptable terms or with adequate coverage against all potential liabilities.

## **Reliance upon Insurers and Governments**

Even if the Company will be able to commercialize pharmaceutical product candidates, the products may not receive adequate reimbursement from government or private pay insurers. Additionally, fluctuations in drug prices caused by governments and insurers could affect the Company's business.

## Intellectual Property

Failure to obtain or register trademarks used or proposed to be used in the business of the Company could require the Company to rebrand, resulting in a material adverse impact on its business. If the Company is unable to register or, if registered, maintain effective patent rights for its product candidates, the Company may not be able to effectively compete in the market. If the Company is not able to protect its proprietary information and know-how, such proprietary information may be used by others to compete against the Company. The Company may not be able to identify infringements of its patents (if and when granted), and, accordingly, the enforcement of its intellectual property rights may be difficult. Once such infringements are identified, enforcement could be costly and time consuming. Third party claims of intellectual property infringement, whether or not reasonable, may prevent or delay the Company's development and commercialization efforts.

The Company's success will depend in part upon its ability to protect its intellectual property and proprietary technologies and upon the nature and scope of the intellectual property protection the Company receives. The ability to compete effectively and to achieve partnerships will depend on its ability to develop and maintain proprietary aspects of the Company's technology and to operate without infringing on the proprietary rights of others. The presence of such proprietary rights of others could severely limit its ability to develop and commercialize its products and to conduct its existing research, and could require financial resources to defend litigation, which may be in excess of the Company's ability to raise such funds. There is no assurance that the Company's patent applications submitted or those that it intends to acquire will be approved in a form that will be sufficient to protect its proprietary technology and gain or keep any competitive advantage that the Company may have or, once approved, will be upheld in any post-grant proceedings brought by any third parties.

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 the Company may be challenged, invalidated or circumvented. To the extent the Company's intellectual property offers inadequate protection, or is found to be invalid or unenforceable, the Company will be exposed to a greater risk of direct competitive position could be adversely affected, as could the Company's 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. The Company will be able to protect its intellectual property from unauthorized use by third parties only to the extent that its proprietary technologies, key products, and any future products are covered by valid and enforceable intellectual property rights, including patents, or are effectively maintained as trade secrets, and provided the Company has the funds to enforce its rights, if necessary.

# Limited Operating History and Lack of Profits

The Company has not yet generated material revenue. The Company has a limited operating history. The Company 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 the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

## Management of Growth

The Company may be subject to growth-related risks, including pressure on its internal systems and controls. The Company's ability to manage its growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. The inability of the Company to deal with this growth could have a material adverse impact on its business, operations and prospects. The Company may experience growth in the number of its employees and the scope of its operating and financial systems, resulting in increased responsibilities for the Company's personnel, the hiring of additional personnel and, in general, higher levels of operating expenses. In order to manage the current operations of the Company and any future growth effectively, the Company will also need to continue to implement and improve its operational, financial and management information systems and to hire, train, motivate, manage and retain its employees. There can be no assurance that the Company will be able to manage such growth effectively, that its management, personnel or systems will be adequate to support the Company's operations or that the Company will be able to achieve the increased levels of revenue commensurate with the increased levels of operating expenses associated with this growth.

#### Dependence on Management Team

The Company will depend on certain key senior managers who have developed strong relationships in the industry to oversee the Company's core marketing, business development, operational and fund-raising activities. Their loss or departure in the short-term would have an adverse effect on the Company's future performance.

# **Conflicts of Interest**

Certain of the directors and officers of the Company will be 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 the Company may become subject to conflicts of interest. The OBCA provides that in the event that a director has a material interest in a contract or proposed contract or agreement that is material to the issuer, the director shall disclose his interest in such contract or agreement and shall refrain from voting on any matter in respect of such contract or agreement, subject to and in accordance with the OBCA. To the extent that conflicts of interest arise, such conflicts will be resolved in accordance with the provisions of the OBCA. To the knowledge of the management of the Company, as at the date hereof there are no existing or potential material conflicts of interest between the Company and a director or officer of the Company except as otherwise disclosed herein.

# **Reliance on Third Parties**

The Company will rely on outside sources to manufacture the psychedelics used in the clinics operated by the Company and further relies on outside sources to stock and distribute, via a prescription by a licensed physician, the psychedelics used in the clinics. The Company will have little to no control over these third parties. The failure of such third parties to deliver either components or finished goods and otherwise perform their obligations on a timely basis could have a material adverse effect on the business of the Company.

#### **Risk Associated with the Capital Markets**

# Market for Securities and Volatility of Share Price

The trading prices of NEO Exchange-listed companies have experienced substantial volatility in the past. The market price of the Common Shares may be adversely affected by a variety of factors relating to the Company's business, including fluctuations in the Company's operating and financial results, the results of any public announcements made by the Company and the Company's failure to meet analysts' expectations. In addition, from time to time, the stock market experiences significant price and volume volatility that may affect the market price of the Common Shares for reasons unrelated to the Company's performance. Additionally, the value of the Common Shares is subject to market value fluctuations based upon factors that influence the Company's operations, such as legislative or regulatory developments, competition, technological change, global capital market activity and changes in interest and currency rates. There can be no assurance that the market price of the Common Shares will not experience significant fluctuations that are unrelated to the Company's performance.

#### **Smaller** Companies

Market perception of junior companies may change, potentially affecting the value of investors' holdings and the ability of the Company to raise further funds through the issue of further Common Shares or otherwise. The share price of publicly traded smaller companies can be highly volatile. The value of the Common Shares may rise or fall and, in particular, the share price may be subject to sudden and large falls in value given the restricted marketability of the Common Shares.

## Speculative Nature of Investment Risk

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

## Liquidity and Future Financing Risk

The Company has limited financial resources, has no source of operating income other than income generated from its clinics, and has no assurance that additional funding will be available to it for further development, operations and expansion plans. Although the Company has been successful in the past in financing activities through the sale of equity securities, there can be no assurance that the Company will be able to obtain additional financing in the future to execute its business plan. Further, current global financial conditions have been subject to increased volatility and access to public financing has been negatively impacted. This may impact the ability of the Company to obtain equity or debt financing in the future and, if obtained, on terms favorable to the Company.

The Company will likely operate at a loss for the foreseeable future and it will require additional financing in order to fund future operations and expansion plans. The Company'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 the Company will be successful in its efforts to secure any additional financing or additional financing on terms satisfactory to management. Moreover, future activities may require the Company to alter its capitalization significantly and, if additional financing is raised by issuance of additional shares of the Company from treasury, control may change and shareholders may suffer dilution. The inability of the Company to access sufficient capital for its operations could have a material adverse effect on the Company's financial condition and results of operations.

# The Company Expects to Incur Future Losses and May Never Become Profitable

The Company has historically incurred losses and expects to incur an operating loss for the year ending January 31, 2023. The Company believes that operating losses will continue as it is planning to incur significant costs associated with the expansion of its clinics, its research and development initiatives and other projects. The Company's net losses have had and will continue to have an adverse effect on, among other things, shareholders' equity, total assets and working capital. The Company expects that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. The Company cannot predict when it will become profitable, if at all.

# Further Issuances or Actual or Potential Sales of Securities

The issue by the Company of Common Shares or other securities convertible into Common Shares could result in significant dilution in the equity interest of existing shareholders and adversely affect the market price of the Common Shares. The Company's articles permit the issue of an unlimited number of Common Shares and an unlimited number of preferred shares and shareholders will have no pre-emptive rights in connection with such further issues of securities of the Company. Also, additional Common Shares may be issued by the Company upon the exercise of stock options and upon the exercise or conversion of other securities convertible into Common Shares. The issue of these additional securities may have a similar dilutive effect on then existing holders of Common Shares.

The market price of the Common Shares could decline as a result of future issuances by the Company, including the issue of securities in connection with strategic alliances, or sales by its existing holders of Common Shares, or the

perception that these sales could occur. Sales of Common Shares by shareholders may also make it more difficult for the Company to sell equity securities at a time and price that it deems appropriate, which could reduce its ability to raise capital and have an adverse effect on its business.

# Negative Cash Flow from Operations

During the financial year ended January 31, 2023, the Company had negative operating cash flow because its revenues did not exceed its operating expenses. In addition, as a result of the Company's business plans for the research and development as well as expansion of clinics, the Company expects to incur significant costs resulting in the cash flow from operations to be negative until revenues improve to offset its operating expenditures. The Company's net losses have had and will continue to have an adverse effect on, among other things, shareholders' equity, total assets and working capital. The Company expects that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. The Company cannot predict when it will become profitable, if at all.

# Dividends

The Company does not anticipate paying any dividends on the Common Shares in the foreseeable future. Dividends paid by the Company would be subject to tax and, potentially, withholdings.

Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, financial results, cash requirements, contractual restrictions and other factors that the Board may deem relevant.

# Enforcement of Civil Liabilities

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

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

# Russian-Ukrainian War

The continued escalation of the Russian-Ukrainian War has resulted in significant volatility in commodity prices and global markets and an increased risk of cybersecurity and information technology attacks. The ongoing war has caused foreign governments, including Canada and the United States, to impose economic sanctions on Russia. While the Company does not operate in Russia and its operational activities are not currently impacted by sanctions, continued volatility could impact the Company's ability to obtain necessary financing and market liquidity. Expansion of the war outside of the Ukraine may adversely impact global markets and commodity prices as well as the ability of the Company to secure the necessary employees and resources to sustain planned operations.

#### **Global Financial Conditions**

Global financial conditions have been subject to continued volatility. Government debt, the risk of sovereign defaults, political instability and wider economic concerns in many countries have been causing significant uncertainties in the markets. Disruptions in the credit and capital markets can have a negative impact on the availability and terms of credit and capital. Uncertainties in these markets could have a material adverse effect on the Company's liquidity, ability to raise capital and cost of capital. High levels of volatility and market turmoil could also adversely impact commodity prices, exchange rates and interest rates and have a detrimental effect on the Company's business.

## **DIVIDENDS AND DISTRIBUTIONS**

The Company does not currently intend to declare any dividends payable to the holders of the Common Shares. The Company has no restrictions on paying dividends, but if the Company generates earnings in the foreseeable future, it expects that they will be retained to finance growth, if any. The Board will determine if and when dividends should be declared and paid in future based upon the Company's financial position at the relevant time. All of the Common Shares will be entitled to an equal share in any dividends declared and paid.

# DESCRIPTION OF CAPITAL STRUCTURE

#### General

The authorized capital of the Company consists of an unlimited number of Common Shares without par value and an unlimited number of preferred shares without par value. As at the date hereof, there are 35,039,135 Common Shares issued and outstanding and no preferred shares are outstanding.

#### **Common Shares**

The following is a summary of the principal attributes of the Common Shares:

*Voting Rights.* The holders of Common Shares are entitled to receive notice of, attend and vote at any meeting of the shareholders of the Company. The Common Shares carry one vote per Common Share. There are no cumulative voting rights, and directors do not stand for re-election at staggered intervals.

*Dividends*. The holders of Common Shares are entitled to receive on a *pro rata* basis such dividends as may be declared by the directors of the Company, out of funds legally available therefor. There are no indentures or agreements limiting the payment of dividends.

*Profits.* Each Common Share is entitled to share *pro rata* in any profits of the Company to the extent they are distributed either through the declaration of dividends or otherwise distributed to shareholders, or on a winding up or liquidation.

*Rights on Dissolution.* In the event of the liquidation, dissolution or winding up of the Company, the holders of Common Shares will be entitled to receive on a *pro rata* basis all of the assets of the Company remaining after payment of all the Company's liabilities.

*Pre-Emptive, Conversion and Other Rights.* No pre-emptive, redemption, sinking fund or conversion rights are attached to Common Shares, and Common Shares, when fully paid, will not be liable to further call or assessment. No other class of shares may be created without the approval of the holders of Common Shares. There are no provisions discriminating against any existing or prospective holder of Common Shares as a result of such shareholder owning a substantial number of Common Shares.

## **Options and Warrants**

As of the date of this AIF, the Company had outstanding obligations to issue up to 3,021,746 Common Shares in respect of stock options under the stock option plan of the Company.

In addition, as of the date of this AIF, the Company had outstanding obligations to issue up to 10,843,884 Common Shares at prices ranging from \$0.63 to \$2.50 per Common Share in respect of warrants to purchase Common Shares which expire at various times between June 16, 2023 and April 26, 2028.

On December 13, 2021, the Company granted 35,172 DSUs to a director of the Company, pursuant to a restricted share unit ("**RSU**") and DSU compensation plan ("**RSU/DSU Plan**") adopted by the Company. The maximum number of awards issuable under the RSU/DSU Plan, together with the number of stock options issuable under the Company's stock option plan, may not exceed 10% of the number of issued and outstanding common shares of the Company upon settlement. As the RSU/DSU Plan remains subject to the approval of the NEO Exchange Inc. and shareholder ratification as at year ended January 31, 2023, no share-based compensation related to the issuance of DSUs has been made in these consolidated financial statements.

# MARKET FOR SECURITIES

# **Common Shares**

The Common Shares are listed on the Neo Exchange under the symbol "AWKN". The following table sets out the high and low closing market prices and the volume traded of the Common Shares on the NEO for each month of the financial year ended January 31, 2023:

Month	High (Cdn\$) <sup>(1)</sup>	Low (Cdn\$) <sup>(1)</sup>	Volume <sup>(1)</sup>
February 2022	2.05	1.70	248,588
March 2022	1.79	1.50	185,593
April 2022	1.65	1.22	330,628
May 2022	1.37	1.13	763,220
June 2022	1.31	0.45	510,911
July 2022	0.98	0.485	437,570
August 2022	0.73	0.50	629,180
September 2022	0.61	0.44	379,621
October 2022	0.50	0.29	316,065
November 2022	0.56	0.25	836,670
December 2022	0.405	0.28	382,963
January 2023	0.38	0.26	294,443

Notes:

(1) Source: <u>https://www.neo.inc/en/live/security-activity/AWKN#!/market-depth</u>

# **Prior Sales**

As of the date of this AIF, other than as disclosed below, the Company does not have any classes of securities outstanding which are not listed or quoted on a marketplace.

# Common Shares

The following table summarizes details of all issuances of Common Shares, in the year ended January 31, 2023, being the most recently completed financial year of the Company:

Date	Securities	Issue Price/ Exercise Price	Number of Securities
March 21, 2022	Common Shares	\$1.60	2,031,250 <sup>(1)</sup>
September 14, 2022	Common Shares	\$0.55	1,880,454 <sup>(1)</sup>
November 16, 2022	Common Shares	\$0.55	3,667,176 <sup>(1)</sup>

Notes:

(1) Issued in connection with a non-brokered private placement.

## Stock Options

The following table sets forth details for all stock options of the Company that were issued under the Company's stock option plan during the year ended January 31, 2023 and thereafter until the date of this AIF, with each stock option exercisable to acquire one Common Share.

Date of Issue	Number of Awakn Options Issued	Exercise Price	Expiry Date
April 25, 2022	11,918	\$2.20	March 21, 2024
May 3, 2022	150,000	\$1.50	May 3, 2024
December 12, 2022	1,000,000(1)	\$0.55	December 12, 2027
December 12, 2022	100,000	\$0.55	December 12, 2023

Notes:

(1) Options vesting 1/3 on December 12, 2022, 1/3 on December 12, 2023 and 1/3 on December 12, 2024.

#### **Warrants**

During the year ended January 31, 2023 and thereafter until the date of this AIF, the Company issued the following warrants to purchase Common Shares, with each warrant exercisable for one Common Share.

Date of Issue	Description	Number of Warrants Issued	Exercise Price	Expiry Date
March 21, 2022	Warrants	1,015,625(1)	\$2.20	March 21, 2024
September 14, 2022	Warrants	1,880,454 (1)	\$0.68	September 14, 2024
September 14, 2022	Broker Warrants	53,200(1)	\$0.68	September 14, 2024
October 25, 2022	Warrants	600,000 <sup>(2)</sup>	\$0.68	October 25, 2024
November 16, 2022	Warrants	3,667,176 <sup>(1)</sup>	\$0.68	November 16, 2024

Notes

(1) Issued in connection with a non-brokered private placement.

(2) Issued to TD Veen AS (the "Lender") in connection with the debt financing agreement between Awakn Norway and the Lender.

## Escrowed Securities and Securities Subject to Contractual Restrictions on Transfer

In connection with the RTO certain shareholders have agreed to lock-up their Common Shares. Certain shareholders have voluntarily extended the lock-ups subsequently such that there are escrow releases as follows on 10,656,556 common shares of the Company:

	Number of		Number of		Number of
Date	Shares	Date	Shares	Date	Shares
23-Mar-23	806,575	31-Mar-25	111,500	31-Mar-27	111,500
04-Apr-23	30,000	30-Jun-25	111,500	30-Jun-27	111,500
23-Jun-23	679,950	30-Sep-25	111,500	30-Sep-27	111,500
23-Sep-23	426,700	31-Dec-25	111,500	31-Dec-27	111,500
23-Dec-23	426,700	31-Mar-26	111,500	31-Mar-28	111,500
31-Mar-24	3,558,103	30-Jun-26	111,500	30-Jun-28	111,500
30-Jun-24	111,500	30-Sep-26	111,500	30-Sep-28	111,500
30-Sep-24	3,558,103	31-Dec-26	111,500	31-Dec-28	111,500
31-Dec-24	111,500				

## **DIRECTORS AND OFFICERS**

# **Directors and Executive Officers**

Other than otherwise indicated, the following table is as of the date of the AIF and sets out the name, municipality of residence, positions and/or offices held with the Company, and principal occupations for the last five years of each person who is a director or executive officer of the Company, as well as the period during which each person has been a director or officer of the Company, as applicable.

Name, Province, Country of Residence and Position(s) with the Company	Principal Occupation for Last Five Years <sup>(1)</sup>	Director or Officer Since	Number of Common Shares Owned <sup>(1)</sup>
Anthony Tennyson President, Chief Executive Officer and a Director Dublin, Ireland	CEO of the Company and previously a Director at Aon	May 21, 2020	1,532,706 <sup>(5)</sup>
Jonathan Held Chief Business Officer, Interim Chief Financial Officer and Secretary Ontario, Canada	CFO of the Company; Partner at ALOE Finance Inc., a consulting firm	April 27, 2020	624,054 <sup>(6)</sup>
Paul Carter Director Wiltshire, United Kingdom	Director: HutchMed PLC; Director: Mallinckrodt Pharmaceuticals PLC; Director : Immatics NV; Director : VectivBio Inc; Evox Therapeutics - Chairman of the Board; and Astorg Partners - Senior Advisor BioPharma	December 14, 2021	Nil
George Scorsis <sup>(3)(4)</sup> Chair of the Board and a Director Ontario, Canada	Executive Chairman of Entourage Health Corp., a cannabis company	May 21, 2020	1,130,725 <sup>(7)</sup>
Stephen Page <sup>(3)(4)</sup> Director London, United Kingdom	Health, social care and education industry consultant	April 12, 2021	68,000
John Papastergiou <sup>(3)(4)</sup> Director Ontario, Canada	Research Scientist and Pharmacist	April 12, 2021	39,250 <sup>(8)</sup>

Name, Province, Country of Residence and Position(s) with the Company	Principal Occupation for Last Five Years <sup>(1)</sup>	Director or Officer Since	Number of Common Shares Owned <sup>(1)</sup>
James Collins Chief Operating Officer London, United Kingdom	COO of the Company and previously Managing Director of Accenture Strategy	January 1, 2021	210,000
Dr. Shaun McNulty Chief Science Officer Essex, United Kingdom	CSO of the Company and previously Chief Scientific Officer of Inflection Biosciences Ltd., a biotech company; Chief Scientific Officer of Biosceptre International Limited, a biotech company	January 11, 2021	Nil
Professor David Nutt Chief Research Officer Bristol, United Kingdom	Edmund J. Safra Professor of Neuropsychopharmacology in the Division of Brain Science, Dept of Medicine, Imperial College London	June 24, 2021	140,250 <sup>(9)</sup>

Notes:

- (1) A more detailed biography of each director and officer of the Company is set out below.
- (2) The information as to voting securities beneficially owned, controlled or directed, not being within the knowledge of the Company, has been furnished by the respective director or officer individually.
- (3) Member of the Audit Committee.
- (4) Member of the Corporate Governance, Nominating and Compensation Committee
- (5) 1,510,706 Common Shares are held by Alpha Tango Ltd, a corporation beneficially owned by Mr. Tennyson, and 22,000 Common Shares are held directly by Mr. Tennyson.
- (6) 84,900 Common Shares are held by 2472199 Ontario Ltd, a corporation beneficially owned by Mr. Held, and 539,154 Common Shares are held directly by Mr. Held.
- (7) 600,000 Common Shares are held by Buyup Holdco Inc., a corporation beneficially owned by Mr. Scorsis, and 530,725 Common Shares are held directly by Mr. Scorsis.
- (8) 31,250 Common Shares are held by John Papastergiou Pharmacy Limited, a corporation beneficially owned by Mr. Papastergiou, and 8,000 Common Shares are held directly by Mr. Papastergiou.
- (9) 140,250 Common Shares are held by Equasy Enterprises Ltd., a corporation beneficially owned by Professor Nutt.

# **Biographies**

#### Anthony Tennyson, Co-founder, President, Chief Executive Officer and a Director

Mr. Tennyson is an experienced professional and financial services industry executive, with over 15 years Risk Consulting and Capital Markets experience. Prior to co-founding Awakn Life Sciences, Anthony worked at Aon plc, a leading global professional services firm providing a range of risk, reinsurance, and health solutions, for 10 years holding a range of senior strategy and commercial roles. Anthony was global head of operations and strategy for Aon's risk consulting division and Anthony also led Aon's Energy and Financial Institutions risk consulting practice groups globally. Prior to Aon, Anthony worked in capital markets for five years with both Merrill Lynch and Bank of Ireland. Anthony holds an MBA in specializing in Strategy and Finance and an MSc in Technology both from University College Dublin's Smurfit Graduate School of Business, Ireland's top ranked business school.

# Jonathan Held, Co-founder, Chief Business Officer, Secretary, Interim Chief Financial Officer and a former Director

Mr. Held, CPA, CA, is a seasoned financial executive with CFO level experience for private / public companies. Mr. Held is a partner at ALOE Finance, a boutique firm specializing in transaction advisory and senior level finance solutions. Mr. Held has worked in a number of sectors including technology, biotech and natural resources, both domestic and international, and has been involved in numerous successful public market transactions including initial public offerings, reverse takeovers and financings. Mr. Held was previously a Director and Chief Financial Officer of Tassili Life Sciences Corp. which focused on mTBI and PTSD research. Mr. Held holds a Bachelor of Mathematics and Masters of Accounting from the University of Waterloo.

#### Paul Carter, Director

Mr. Carter is a seasoned international leader with an outstanding and proven track record in the BioPharma space. He has lived and worked extensively in the US, Europe and Asia and continues to be strongly networked and professionally connected to a diverse range of publicly listed and private life science orientated businesses in these territories. Currently, Mr. Carter is a director and committee chair of four BioPharma companies listed in the United States: HutchMed PLC, Mallinckrodt Pharmaceuticals, Immatics NV, and VectivBio Inc. Prior to this, Mr. Carter served as Executive Vice-President and Chief Commercial Officer of Gilead Sciences Inc., where he was responsible for the company's worldwide commercial activity, including \$33 billion of revenue in 2015.

## George Scorsis, Co-founder, Chair of the Board and a Director

Mr. Scorsis has over 25 years of experience leading companies in highly regulated industries to rapid growth, including alcohol, energy drinks and, most recently, medical cannabis. While attending York University, completing his Bachelor in Administrative Studies, Mr. Scorsis worked as a University Ambassador for Bacardi Canada and held several executive roles. Following York University, Mr. Scorsis obtained an MBA at Queens University. Mr. Scorsis, formerly President of Red Bull Canada, was instrumental in restructuring the organization from a geographical and operational perspective, growing the business to \$150 million in revenue. He also worked closely with Health Canada on guidelines regulating the energy drink category. Mr. Scorsis also brings agricultural and technological experience from his time as President at Mettrum Health Corp., which was acquired for \$473 million by Canopy Growth Corporation. Mr. Scorsis was also the CEO and Director of Liberty Health Sciences Inc., which was one of the first Canadian cannabis companies to expand into the United States. He also served as Chairman of the Board of Directors of Scythian Biosciences Corp., a research and development company committed to advancing treatment efforts for traumatic brain injury with its proprietary cannabinoid-based combination drug therapy and additional cannabis-related activities across the globe as well as the former Chairman of Entourage Health Group.

## Stephen Page, Director

Mr. Page is an experienced healthcare executive and board member, having significant experience working with both the National Health Service ("**NHS**"), and private enterprises in the United Kingdom. Mr. Page worked in the NHS for fifteen years and was the first CEO of Oxleas NHS Trust from 1993 through 1998, which focused on mental health and learning difficulties. From 1998 to 2005, Mr. Page worked on the board of directors of a number of private sector companies, including Priory Healthcare and Nestor plc. In 2005, Mr. Page was the CEO of Acorn Care and Education, which he grew through acquisitions and organic growth to become a leading national provider of special needs education and foster care resulting in the eventual sale to the Ontario Teachers' Pension Plan in 2010. Mr. Page currently consults within the health, social care and education industry and acts as an executive coach seeking to promote high quality leadership and management in the sector. Mr. Page also acts as the Chair of Sequence Care, New Reflections and Brain in Hand. Mr. Page holds an MBA from London Business School and a Business Studies Degree from Sheffield University.

#### John Papastergiou, Director

Professor Papastergiou is an experienced clinical research scientist and pharmacist. He has served as an advisor to many large pharmaceutical organizations including Bayer, Pfizer, GSK, and Astra Zeneca and he owns and operates four large community pharmacies in Canada. Prof. Papastergiou's innovative research in the area of point-of-care diagnostic testing and pharmacogenomics has led to the development and advancement of a number of tech start-up companies of which he has sat on the board of directors. Prof. Papastergiou holds Faculty appointments at the schools of Pharmacy at each of the University of Toronto and the University of Waterloo. Prof. Papastergiou has won a number of awards including Canadian Pharmacist of the Year. In 2019, he was named by the International Forum on Advancement of Healthcare as one of the top 100 healthcare leaders globally and was also presented with the Ontario Pharmacists' Association Award for Excellence in Research and Academia. Prof. Papastergiou holds multiple degrees including a PhD from Rhabdoud University, Netherlands. He is a sought after speaker, author, and media personality participating at events in over 30 countries.

### James Collins, Chief Operating Officer

Mr. Collins is a senior business leader and mental health champion with 17 years of experience with Accenture Strategy, 7 years as Managing Director, designing and delivering corporate, digital and operating model strategies. James is an industry thought leader with several publications on digital innovation and the transformation of industries, including major studies in collaboration with the World Economic Forum. While at Accenture James was a champion for Inclusion, Diversity & Mental Health driving awareness and structural change to address inequity in the workplace. James holds a BSc and MPhil in Psychology from University College London (UCL), and a Foundation Certificate in Psychotherapy, Counselling & Coaching from the New School of Psychotherapy and Counselling (NSPC).

## Dr. Shaun McNulty, Chief Scientific Officer

Dr. McNulty is an experienced drug development expert who has worked in and consulted for pharmaceutical and biotechnology companies for over 25 years. After obtaining a D.Phil. in CNS cell signalling from the University of York, he undertook post-doctoral studies at the University of Cambridge, researching neuronal cell signalling and molecular regulation of circadian physiology. Dr McNulty's industrial career began managing research and drug development teams and projects first for Pfizer and then for GSK Neuroscience departments. Dr McNulty then moved into the biotechnology sector, managing portfolios and product development activities for both Syntaxin and ImmBio. Shaun went on to lead all research and drug development activities for Biosceptre and Inflection Biosciences as CSO. His career has focused on the identification, development and translation of innovative therapeutics, from target identification and characterization, to obtaining regulatory clearance for and managing clinical trials.

## Professor David Nutt, Chief Research Officer

Prof. Nutt is a psychiatrist and the Edmund J. Safra Professor of Neuropsychopharmacology in the Division of Brain Science, Dept of Medicine, Imperial College London where he uses a range of brain imaging techniques to explore the causes of addiction and other psychiatric disorders and to search for new treatments. Prof. Nutt has published over 400 original research papers, a similar number of reviews and books chapters, eight government reports on drugs and 28 books, including one for the general public entitled "*Drugs: Without The Hot Air*", that won the Transmission Prize in 2014.

Prof. Nutt is currently the President of the European Brain Council and Founding Chair of Drug Science. Previously he held the position of President of the British Association of Psychopharmacology, the British Neuroscience Association, and the European College of Neuropsychopharmacology. He broadcasts widely to the general public both on radio and television. In 2010, The Times Eureka science magazine voted him one of the 100 most important figures in British Science, and the only psychiatrist on the list. In 2013, Prof. Nutt was awarded the John Maddox Prize from Nature/Sense about Science for standing up for science.

Each of the directors of the Company is appointed for a one-year term expiring at each annual meeting of shareholders or until their successors are elected or appointed.

As at the date of this AIF, the current directors and senior executive officers of the Company as a group beneficially own, directly or indirectly, or exercise control or direction over, approximately 3,744,985 Common Shares representing [•]% of the outstanding number of Common Shares. The information as to Common Shares beneficially owned or over which control or direction is exercised, not being within the knowledge of the Company, has been furnished by the directors and executive officers directly.

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

#### Corporate Cease Trade Orders or Bankruptcies

No director or executive officer of the Company is, as at the date of this AIF, or was within 10 years before the date of this AIF, a director, chief executive officer or chief financial officer of any company that:

- (a) was subject to: (i) a cease trade order; (ii) an order similar to a cease trade order; or (iii) an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days (collectively an "**Order**") and that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or
- (b) was subject to an Order that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

No director or executive officer is, as at the date of this AIF, or was within 10 years before the date of this AIF, a director or executive officer of any company that, while the director or executive officer was acting in that capacity, or within a year of the director or executive officer 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.

# Personal Bankruptcies

No director or executive officer of the Company, or a securityholder anticipated to hold sufficient securities of the Company to affect materially the control of the Company, or a personal holding company of any such persons, has, within the 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director, officer or promoter.

# Penalties and Sanctions

No director or executive officer of the Company, or a securityholder anticipated to hold a sufficient number of securities of the Company to affect materially the control of the Company, has

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

# **Conflicts of Interest**

Directors and officers of the Company may also serve as directors and/or officers of other companies and may be presented from time to time with situations or opportunities which give rise to apparent conflicts of interest which cannot be resolved by arm's length negotiations but only through exercise by the officers and directors of such judgment as is consistent with their fiduciary duties to the Company which arise under applicable corporate law, especially insofar as taking advantage, directly or indirectly, of information or opportunities acquired in their capacities as directors or officers of the Company. It is expected that all conflicts of interest will be resolved in accordance with the BCBCA. It is expected that any transactions with officers and directors will be on terms consistent with industry standards and sound business practice in accordance with the fiduciary duties of these persons to the Company, and, depending upon the magnitude of the transactions and the absence of any disinterested board members, may be submitted to the shareholders for their approval.

# AUDIT COMMITTEE INFORMATION REQUIRED IN AN AIF

National Instrument 52-110 - Audit Committees ("NI 52-110") requires that certain information regarding the audit committee of an issuer be included in an AIF.

## Audit Committee Charter

The full text of the charter of the Audit Committee of the Company is attached as schedule A to this AIF (the "Audit Committee Charter").

## Composition of the Audit Committee

The Audit Committee members of the Company are George Scorsis, Stephen Page and John Papastergiou, each of whom is a director, financially literate and independent in accordance with NI 52-110.

## **Relevant Education and Experience**

The following is a description of the education and experience of each member of the Audit Committee that is relevant to the performance of his responsibilities as an Audit Committee member and, in particular, any education or experience that would provide the member with:

- 1. an understanding of the accounting principles used by the Company to prepare its consolidated financial statements;
- 2. the ability to assess the general application of such accounting principles in connection with the accounting for estimates, accruals and reserves;
- 3. experience preparing, auditing, analyzing or evaluating consolidated financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the Company's consolidated financial statements, or experience actively supervising one or more persons engaged in such activities; and
- 4. an understanding of internal controls and procedures for financial reporting.

*George Scorsis, Chair of the Board and Director* – Mr. Scorsis has over 25 years of experience leading companies in highly regulated industries to rapid growth, including alcohol, energy drinks and, most recently, medical cannabis. While attending York University, completing his Bachelor in Administrative Studies, Mr. Scorsis worked as a University Ambassador for Bacardi Canada and held several executive roles. Following York University, Mr. Scorsis obtained an MBA at Queens University. Mr. Scorsis, formerly President of Red Bull Canada, was instrumental in restructuring the organization from a geographical and operational perspective, growing the business to \$150 million in revenue. He also worked closely with Health Canada on guidelines regulating the energy drink category. Mr. Scorsis also brings agricultural and technological experience from his time as President at Mettrum Health Corp., which was acquired for \$473 million by Canopy Growth Corporation. Mr. Scorsis was also the CEO and Director of Liberty Health Sciences Inc., which was one of the first Canadian cannabis companies to expand into the United States. He also served as Chairman of the Board of Directors of Scythian Biosciences Corp., a research and development company committed to advancing treatment efforts for traumatic brain injury with its proprietary cannabinoid-based combination drug therapy and additional cannabis-related activities across the globe as well as the former Chairman of Tassili Life Sciences Corp. which focusses on PTSD research. Mr. Scorsis is currently the Executive Chairman of Entourage Health Corp.

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New Reflections and Brain in Hand. Mr. Page holds an MBA from London Business School and a Business Studies Degree from Sheffield University.

John Papastergiou, Director – Professor Papastergiou is an experienced clinical research scientist and pharmacist. He has served as an advisor to many large pharmaceutical organizations including Bayer, Pfizer, GSK, and Astra Zeneca and he owns and operates four large community pharmacies in Canada. Prof. Papastergiou's innovative research in the area of point-of-care diagnostic testing and pharmacogenomics has led to the development and advancement of a number of tech start-up companies of which he has sat on the board of directors. Prof. Papastergiou holds Faculty appointments at the schools of Pharmacy at each of the University of Toronto and the University of Waterloo. Prof. Papastergiou has won a number of awards including Canadian Pharmacist of the Year. In 2019, he was named by the International Forum on Advancement of Healthcare as one of the top 100 healthcare leaders globally and was also presented with the Ontario Pharmacists' Association Award for Excellence in Research and Academia. Prof. Papastergiou holds multiple degrees including a PhD from Rhabdoud University, Netherlands. He is a sought-after speaker, author, and media personality participating at events in over 30 countries.

## Audit Committee Oversight

Since the commencement of the Company's most recently completed financial year, there has not been a recommendation of the Audit Committee to nominate or compensate an external auditor which was not adopted by the Board.

## Reliance on Exemptions in NI 52-110

Since the commencement of the Company's most recently completed financial year, the Company has not relied on:

- 1. the exemption in section 2.4 (*De Minimis Non-audit Services*) of NI 52-110;
- 2. the exemption in section 3.2 (*Initial Public Offerings*) of NI 52-110;
- 3. the exemption in subsection 3.3(2) (*Controlled Companies*) of NI 52-110;
- 4. the exemption in section 3.4 (*Events Outside Control of Member*) of NI 52-110;
- 5. the exemption in section 3.5 (*Death, Incapacity or Resignation of Audit Committee Member*) of NI 52-110;
- 6. the exemption in section 3.6 (*Temporary Exemption for Limited and Exceptional Circumstances*) of NI 52-110;
- 7. the exemption in subsection 3.8 (Acquisition of Financial Literacy) of NI 52-110; or
- 5. an exemption from the requirements of NI 52-110, in whole or in part, granted by a securities regulator under Part 8 (*Exemptions*) of NI 52-110.

#### **Pre-Approval Policies and Procedures**

The Audit Committee is expected to adopt specific policies and procedures for the engagement of non-audit services as described in the Audit Committee Charter.

# Audit Fees

The following table provides details in respect of audit, audit related, tax and other fees billed by the external auditor of the Company for professional services rendered to the Company during the fiscal year ended January 31, 2023 and January 2022:

Year Ended	Audit Fees (\$)	Audit-Related Fees (\$)	Tax Fees (\$)	All Other Fees (\$)
January 31, 2023	153,000	36,000	Nil	Nil
January 31, 2022	98,000	69,923	Nil	Nil

Audit Fees – aggregate fees billed for professional services rendered by the auditor for the audit of the Company's annual consolidated financial statements as well as services provided in connection with statutory and regulatory filings.

Audit-Related Fees – aggregate fees billed for professional services rendered by the auditor and were comprised primarily of audit procedures performed related to the review of quarterly consolidated financial statements and related documents.

Tax Fees – aggregate fees billed for tax compliance, tax advice and tax planning professional services. These services included reviewing tax returns and assisting in responses to government tax authorities.

All Other Fees – aggregate fees billed for professional services which included accounting advice.

# PROMOTERS

Other than Anthony Tennyson, Chief Executive Officer of the Company and Jonathan Held, Interim CFO and Chief Business Officer of the Company (collectively the "**Promoters**"), no person or company has been, within the two most recently completed financial years or during the current financial year, a promoter of the Company. Information regarding the Promoters and their security holdings in the Company is set forth in the AIF under the heading "*Directors and Officers*" (pages 43 to 47).

For his services as the Chief Executive Officer of the Company, Mr. Tennyson receives an annual fee of €175,000 and Mr. Held, for his services as the Chief Financial Officer of the Company, receives and annual fee of \$150,000. In addition, the Company will pay ALOE Finance Inc., a company where Mr. Held is a Partner, an annual fee of \$60,000 for accounting services provided by ALOE Finance Inc. to the Company and a monthly administration fee. Each Promoter is also eligible to receive annual bonuses, as determined by the directors of the Company from time to time, and to be granted stock options under the stock option plan of the Company. As of the date hereof, Mr. Tennyson holds 200,000 stock options to acquire Common Shares exercisable at a price of \$1.20 per Common Share until March 8, 2026 and 225,000 stock options to acquire Common Shares exercisable at a price of \$0.55 per Common Share until December 12, 2027. Mr. Held holds 150,000 stock options to acquire Common store options to acquire Common Shares exercisable at a price of \$1.20 per Common Share until March 8, 2026, and 225,000 stock options to acquire Common store acquire Common Shares exercisable at a price of \$0.55 per Common Share until March 8, 2026, and 225,000 stock options to acquire Common store acquire Common Shares exercisable at a price of \$1.20 per Common Share until March 8, 2026, and 225,000 stock options to acquire Common Shares exercisable at a price of \$1.20 per Common Share until March 8, 2026, and 225,000 stock options to acquire Common Shares exercisable at a price of \$1.20 per Common Share until March 8, 2026, and 225,000 stock options to acquire Common Shares exercisable at a price of \$1.20 per Common Share until March 8, 2026, and 225,000 stock options to acquire Common Shares exercisable at a price of \$0.55 per Common Share until December 12, 2027. As at the date hereof, neither Promoter received a bonus.

# LEGAL PROCEEDINGS

The Company was not party to any legal proceedings or regulatory action during the year ended January 31, 2023. Management is not aware of any contemplated material legal proceedings which it or any of its properties is the subject of.

# INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as disclosed in this AIF, to the knowledge of the Company, no director or executive officer, or person or company that beneficially owns, or controls and directs, directly or indirectly, more than 10% of the any class or series of the voting securities of the Company, or any associate or affiliate of the foregoing, have had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year prior to the date of this AIF that has materially affected or is reasonably expected to materially affect the Company.

# TRANSFER AGENTS AND REGISTRAR

Endeavor Trust Corporation in Vancouver, British Columbia, is the transfer agent and registrar for the Common Shares.

## MATERIAL CONTRACTS

The Company has not entered into any material contracts during the most recently completed financial year or prior financial years which are still in force and effect and which may reasonably be regarded as presently material.

### **INTEREST OF EXPERTS**

The following persons or companies are named as having prepared or certified a report, valuation, statement or opinion described or included in a filing, or referred to in a filing, made under National Instrument 51-102 - Continuous Disclosure Obligations by the Company during, or relating to, the Company's most recently completed financial year, and whose profession or business gives authority to the report, valuation, statement or opinion made by the person or company.

#### Names of Experts

Name	Description
MNP LLP	Independent Auditor; Audit Report dated April 27, 2023 with respect to the financial statements as at January 31, 2023.

To the knowledge of the Company, each of the aforementioned persons or companies did not hold any of the outstanding securities of the Company when they prepared the reports referred to above or following the preparation of such reports. None of the aforementioned persons or companies received any direct or indirect interest in any securities of the Company in connection with the preparation of such reports.

# **ADDITIONAL INFORMATION**

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

Additional financial information is also provided in the Company's audited consolidated financial statements and MD&A for the year ended January 31, 2023, which may also be found on SEDAR at www.sedar.com under the Company's profile.