

Psyence Group Inc.

Management Discussion & Analysis (MD&A) for the three months and six months ended September 30, 2023

> Date of the MD&A: November 10, 2023

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# Psyence Group Inc.

## Management Discussion & Analysis

# Dated: November 09, 2023

The following information should be read in conjunction with the unaudited consolidated financial statements for the period ended September 30, 2023 of Psyence Group Inc. (the **"Company"** or **"Psyence"**), which are prepared in accordance with International Financial Reporting Standards (**"IFRS"**). All figures are expressed in Canadian dollars unless otherwise indicated.

## Forward-Looking Information

This Management Discussion & Analysis ("**MD&A**") contains forward-looking statements and forward-looking information as such terms are defined under applicable Canadian securities laws. These forward-looking statements and forward-looking information include, but are not limited to, statements with respect to management's expectations regarding the future growth, results of operations, performance and business prospects of the Company, and relate to, without limitation:

- the Company's research and development plans, business model, strategic objectives and growth strategy;
- the Company's future growth plans;
- anticipated trends and challenges in the Company's business and the markets in which it operates;
- the future demand for psilocybin and psilocybin mushroom products from time to time produced, supplied, or distributed by the Company;
- the Company's expectations regarding regulatory requirements and developments in the jurisdictions in which it operates;
- the approval of regulatory bodies of psychedelic substances including psilocybin for the treatment of various health conditions;
- controlled substances laws;
- the Company's ability to obtain the issue and/or renewal of licenses and regulatory authorizations for its business operations;
- the Company's estimate of the size of the potential markets for its products;
- the Company may not develop its product and service offerings in a manner that enables it to be profitable and meet its customers' requirements;
- risks that its growth strategy may not be successful;
- risks that fluctuations in its operating results will be significant relative to its revenues;
- risks relating to an evolving regulatory regime related to psilocybin and psychedelic products;
- risks relating to operations based in its emerging markets;
- the continuation of the Company as a going concern;
- the Company's intellectual property;
- the growth of competition from other companies in the industry;
- the Company's actual financial position and results of operations may differ materially from the expectations of the Company's management;
- the Company's exposure to fluctuations in foreign currencies; and
- the Company's expectations regarding the sufficiency of its cash for funding non-development related expenditures and future cash balances.

These forward-looking statements and forward-looking information may also include other statements that are predictive in nature, or that depend upon or refer to future events or conditions. Without



limitation, the words "may", "will", "would", "should", "could", "expect", "plan", "intend", "trend", "indicate", "assume", "anticipate", "believe", "estimate", "predict", "likely" or "potential", or the negative or other variations of these words or other comparable words or phrases, are intended to identify forward-looking statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Forward-looking statements and forward-looking information are not historical facts but instead represent management's expectations, estimates and projections regarding future events.

With respect to forward-looking statements and forward-looking information contained in this MD&A, assumptions have been made regarding, among other things: future research and development plans for the Company proceeding substantially as currently envisioned, future expenditures to be incurred by the Company, research and development and operating costs, additional sources of funding, the impact of competition on the Company and the Company being able to obtain financing on acceptable terms.

Although management believes the expectations reflected in such forward-looking statements and forward-looking information are reasonable, forward-looking statements and forward-looking information are based on the opinions, assumptions and estimates of management at the date the statements are made, and are subject to a variety of risks and uncertainties and other factors that could cause actual events or results to differ materially from those projected in the forward-looking statements and forward-looking information.

These risks, uncertainties and factors include, but are not limited to: risks, uncertainties and the results of the growth and cultivation of psilocybin or the development of the Company's future products and the timing thereof; the Company may not have sufficient capital to achieve its growth strategy; risks that its growth strategy may not be successful; regulatory policies concerning psilocybin products; development of laws governing controlled substances; the ability to obtain the issuance of and/or renewal of and/or approvals for licences and authorizations; the Company's plan to conduct research for psilocybin products in Canada, Australia and the United Kingdom and obtaining the requisite regulatory approvals therefore; the Company's expansion of its Lesotho-based production and processing facility; competition from other companies; clinical trial results; limitations on insurance coverage; the timing and amount of estimated capital expenditure in respect of the business of the Company; operating expenditures; success of marketing activities; estimated budgets; currency fluctuations; requirements for additional capital; the timing and possible outcome of litigation in future periods; goals; strategies; future growth; planned business activities and planned future acquisitions; the adequacy of financial resources; and other events or conditions that may occur in the future.

In addition, if any of the assumptions or estimates made by management prove to be incorrect, actual results and developments are likely to differ, and may differ materially, from those expressed or implied by the forward-looking statements contained in, or incorporated by reference into, this MD&A. Accordingly, readers are cautioned not to place undue reliance on such statements.

All of the forward-looking statements and forward-looking information in this MD&A are qualified by these cautionary statements. Statements containing forward-looking statements and/or forward-looking information contained herein are made only as of the date hereof. The Company expressly disclaims any obligation to update, revise or alter statements containing any forward-looking statements or forward-looking information, or the factors or assumptions underlying them, whether as a result of new information, future events or otherwise, except as required by law. New factors emerge from time to time, and it is not possible for the Company to predict which factors may arise. In addition, the Company cannot assess the impact of each factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements or forward-looking information.

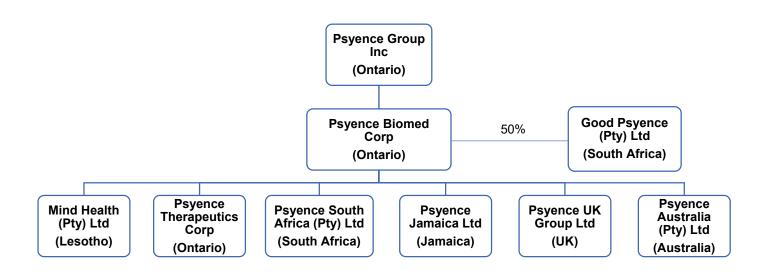


# <u>Overview</u>

# Corporate Structure

The Company is a life science biotechnology company listed on the Canadian Securities Exchange (CSE:PSYG) and quoted on the OTCQB (OTCQB: PSYGF), with a focus on natural psychedelics. Psyence develops natural psilocybin products for the healing of psychological trauma and its mental health consequences in the context of palliative care. We have commenced the clinical trial process to evaluate the safety and efficacy of its drug candidates.

The below diagram shows the corporate structure of Psyence Group Inc.



# Development of the business

Psyence Biomed Corp. ("**PBC**") was a private corporation incorporated under the laws of British Columbia on May 21, 2020. Effective July 21, 2023 PBC was continued under the laws of the Province of Ontario.

The Psyence Group was created through a business combination of Psyence Biomed Corp. with Cardinal Capital Partners Inc., a public company, in January 2021, resulting in PSYG's public listing in Canada.

Mind Health (Pty) Ltd (**"MindHealth Lesotho"**) is a private entity incorporated under the laws of the Kingdom of Lesotho, which in May 2020, was granted permission by the Minister of Health (Lesotho) to import, cultivate, produce, manufacture and export psilocybin mushrooms. The governmentally licensed commercial psilocybin cultivation and production facilities operated by MindHealth Lesotho under the name "Psyence Production" are situated in the Kingdom of Lesotho. On May 22, 2020, MindHealth Lesotho became a subsidiary of MindHealth.

# Listing on CSE and director changes

The Company listed on the Canadian Securities Exchange ("CSE") on January 27, 2021.

The board of directors and management of the Company are comprised of Jody Aufrichtig (Chairman), Marvin Singer, Alan Friedman and Dr. Neil Maresky. Effective July 11, 2023 Christopher Bull was appointed as director of the Company.



# Psyence Biomed Corp and subsidiaries post CSE listing

Psyence South Africa (Pty) Ltd (**"PSA"**) is a private corporation incorporated under the laws of South Africa on April 12, 2021. PSA is a wholly owned subsidiary of PBC.

Good Psyence (Pty) Ltd (**"Good Psyence"**) is a private corporation incorporated under the laws of South Africa on May 5, 2021. PBC owns 50% of Good Psyence in a joint venture. The joint venture launched a functional mushroom brand, "GOODMIND", and is responsible for the production, commercialization and sale of the products.

Psyence Jamaica Ltd (**"Psyence Jamaica"**) is a private corporation incorporated under the laws of Jamaica on May 11, 2021. Psyence Jamaica is a wholly owned subsidiary of PBC. Psyence Jamaica has not had any activity to date and no future operating activity is expected as the Company will conduct future product development in Australia, the UK and Canada in line with future clinical trials. The Company has filed a request for Psyence Jamaica to be removed from the list of registered companies appearing on the company register with the Companies Office of Jamaica.

Psyence UK Group Ltd. (**"Psyence UK"**) is a private corporation incorporated under the laws of England and Wales on March 18, 2022. Psyence UK is a wholly owned subsidiary of PBC.

On February 15, 2023 the Company incorporated a wholly owned subsidiary called "Psyence Australia (Pty) Ltd." in Victoria, Australia (**"Psyence Australia"**). This subsidiary was incorporated to conduct the clinical trial in Australia (described below) and apply for the Australian Federal Government's Research & Development tax incentive program, which could provide up to a 43.5% rebate on Psyence's research and development expenses in Australia as described below.

# Outstanding Share Data

Security	As of September 30, 2023	At date of this MD&A
Common Shares	133,287,854	137,438,182
Options	3,730,901	3,730,901
Warrants	14,602,671	14,602,671
Restricted Share Units ("RSUs")	5,423,570	4,928,570
Common Shares on a fully diluted basis	157,044,997	160,700,325

# **Business Overview**

The Company has three key divisions: Psyence Therapeutics, Psyence Function and Psyence Production. It has received independent local legal opinions during the latter half of the 2021 calendar year in Canada, United Kingdom and Lesotho confirming the lawfulness of the Company's activities as well as its compliance with material legal, regulatory and governmental developments as they pertain to and affect the Company's operations. The Company's operations are conducted in compliance with local laws where such activities are permissible and either (a) do not require any specific legal or regulatory approvals, or (b) the Company has obtained all necessary legal and/or regulatory approvals. The three key divisions of the Company are described below:

# 1. Psyence Therapeutics

Psyence strives to set the global standard for excellence and consistency in drug development using nature-based psilocybin products. The Company's priority is developing pharmaceutical grade psilocybin to help heal psychological trauma and the diagnosable disorders that can result therefrom, including adjustment disorder ("AjD"), anxiety, depression, post-traumatic stress disorder ("PTSD"), and grief and bereavement, especially in the context of palliative care. Our focus includes therapeutic protocols for medical and scientific research including observational studies. Sales of psilocybin containing products for recreational purposes is strictly prohibited and not contemplated by the Company.

Psyence intends to use its own natural psilocybin products cultivated at the Psyence Production Facility for proprietary research and pharmaceutical drug development in other indications, excluding those



specific to palliative care. In addition to the use of licensed drug candidate PEX010 (as described below), Our research and development ("**R&D**") priorities are on developing pharmaceutical preparations of psilocybin doses to help heal the psychological trauma and the diagnosable disorders that can result therefrom as referred to above.

Psyence has contracted iNGENū Pty Ltd ("iNGENū"), a contract research organization ("CRO") in Australia that specializes in the study of psychedelics, to conduct a Phase IIb double-blind, randomized, low-dose controlled clinical trial to assess the efficacy and safety of PEX010 (25mg drug candidate licensed from Filament Health Corp., a Canadian company that produces natural psilocybin capsules ("Filament") in psilocybin-assisted psychotherapy for the treatment of AjD due to incurable cancer ("Palliative Care Clinical Trial"). The Company has entered into an agreement with Filament for the licensing of PEX010 and its associated intellectual property, as well as for the supply of PEX010 for the specific intention of the clinical development of the product, and ultimately, for the marketing authorization for PEX010's use in palliative care.

On January 9, 2023 the Company announced that it had entered into a definitive business combination agreement (the **"Business Combination Agreement"**) with Newcourt Acquisition Corp (NASDAQ: NCAC), a special purpose acquisition company (**"SPAC"**) formed for the purpose of acquiring or merging with one or more businesses (**"Newcourt"**). Newcourt has entered into the Business Combination Agreement with Psyence Biomed Corp., a wholly owned subsidiary of the Company and also referred to as the Psyence Therapeutics division, in order to create a public company (in this case **"PubCo"**) leveraging natural psilocybin in the treatment of palliative care (**"Business Combination"**). This Business Combination Agreement was amended and restated on July 31<sup>st</sup>, 2023.

If the Business Combination is completed, Psyence will continue to be listed on the Canadian Securities Exchange (the **"CSE"**), and will continue to own and operate its other divisions being Psyence Production and Psyence Function. PubCo would be capitalized with a minimum of USD\$20 million, and have access to Nasdaq listed Newcourt shareholders, promoters and advisors. These resources are expected to provide PubCo with the capital to advance natural psilocybin into a Phase IIb Study to be conducted under an approved protocol in Australia, and to engage with the FDA and other regulatory agencies for PhIII registration studies.

The Palliative Care Clinical Trial, along with its associated assets, contracts and intellectual property will constitute the business assets being held by Pubco following the Business Combination. As stated above, the balance of Psyence's business, being the Psyence Function and Psyence Production divisions, as described below will continue to be held by Psyence.

# 2. Psyence Function

Psyence Function is focussed on the development, distribution and sale of legal over-the-counter nonpsilocybin containing functional mushroom nutraceuticals. The team and its joint venture partner are experienced in building brands and in establishing a channel mix for global wellness products. Psyence's first non-psilocybin containing functional mushroom product, GOODMIND<sup>™</sup>, was launched online on August 18, 2021 through its South African-based joint venture, Good Psyence. Good Psyence is a 50/50 joint venture between PBC and The Goodleaf Company (Pty) Ltd (**"Goodleaf"**), a producer of wellness products based in South Africa with established distribution lines through retail stores, online, wholesale, and deli and coffee shops.

# 3. Psyence Production

Psyence has built and operates one of the first federally licensed commercial psilocybin cultivation and production facilities in the world, located in Lesotho, Southern Africa. Our expertise is in the production of certified, pharmaceutical-quality psilocybin - yielding mushrooms. The Psyence Production Facility has been designed and constructed to The British Standards Institute (**"BSI"**) and Good Manufacturing Practice (**"GMP"**) standards. The facility was International Organization for Standardization (**"ISO"**) 22000:2018 certified by the BSI in February 2022. It is equipped with technology and specialized equipment to ensure optimum growing conditions and efficient harvesting and packaging.

Psyence Production has a focus on extraction, production and R&D with strategic partners. It is working



towards providing standardized natural pharmaceutical grade psilocybin products to clinicians, research centres and universities undertaking research and clinical trials in the use of natural psilocybin for the treatment of a range of mental health disorders and other medical conditions.

# **Discussion of operations**

# Stage of Development

Psyence is an early-stage drug development bio-life sciences company. The Psyence Therapeutics division is focused on research and development of registered psilocybin drugs, while the Psyence Production Facility grows ISO 22000:2018 BSI certified mushrooms for Psyence Therapeutics, research centres and universities. Any future revenue will be dependent on a number of factors, including the outcome of the Company's clinical trials, its production facility certifications and yields, demand for GMP produced ISO certified natural psilocybin and the receipt of all required regulatory approvals and licences. Psyence Function has generated revenue through Good Psyence and the sale of the GOODMIND<sup>™</sup> products.

# Good Psyence

Good Psyence generated \$15,293 of revenue, and cost of sales of \$11,092, other income of \$50,239 and a foreign currency loss of \$309 was incurred for the period ended September 30, 2023.

Good Psyence has an agreement in place with Goodleaf to make use of its third-party suppliers and distribution and sales infrastructure.<sup>1</sup> The Company ensures that the suppliers are fulfilling their requirements under their respective supplier agreements and that the suppliers maintain all necessary licences and approvals necessary to perform their obligations under such agreements.

The product line (GOODMIND<sup>TM</sup>) was launched in South Africa under applicable South African law. Please refer to "*Regulatory Framework and Licensing Regime – South Africa*" below for more information. Good Psyence launched the GOODMIND<sup>TM</sup> product on the digital platform <u>www.foragoodmind.com</u> that was registered and developed by Goodleaf solely for the sale of such products. GOODMIND<sup>TM</sup> is also distributed through the digital platforms of Goodleaf, Takealot and Wellness Warehouse as well as Wellness Warehouse stores. Please refer to "*Regulatory Framework and Licensing Regime – South Africa – Online Sales*" below for more information on the regulation of the online sale of GOODMIND<sup>TM</sup> in South Africa. The Company has no intention of selling psychedelic mushrooms commercially in any jurisdiction through e-commerce.

Good Psyence launched the first GOODMIND Functional Mushroom Sachet<sup>2</sup> with the coffee chain Vida E Caffe in South Africa in the third week of November 2021.

# **Non-Revenue Generating Projects**

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

- a. Palliative Care Clinical Trial
- b. Psyence Production Facility

# Palliative Care Clinical Trial

On January 9, 2023 it was announced that Psyence and iNGENū, a CRO in Australia that specializes in the study of psychedelics, had signed a letter of intent to further develop Psyence's licensed natural psilocybin drug product (PEX010), starting with a Phase IIb study and to conduct a pre-IND meeting with the FDA (the Palliative Care Clinical Trial). The product to be used in this Phase IIb trial will be the proprietary botanical drug candidate PEX010. The planned randomised double-blind study will evaluate the use of 2 dosing levels (high 25mg and medium 10mg) of psilocybin assisted psychotherapy versus low-dose(1mg) psilocybin and psychotherapy and will use FDA-recommended primary endpoints to test

<sup>&</sup>lt;sup>2</sup> The third-party supplier of Goodleaf is Joypak (Pty) Ltd for the GOODMIND Functional Mushroom sachets.



<sup>&</sup>lt;sup>1</sup> The third-party supplier of Goodleaf is Afriplex (Pty) Ltd for the GOODMIND capsules.

natural psilocybin (PEX010) in over 84 patients with adjustment disorder. The parties entered into a Master Services Agreement on March 21, 2023 (**"iNGENū MSA"**) in terms of which iNGENū will be responsible for jointly designing Psyence's Palliative Care Clinical Trial. The trial will be carried out in accordance with the requirements of the Therapeutic Goods Administration of the Commonwealth of Australia as well as other international guidelines that relate to clinical investigations and the conduct of clinical research.

Previously, on September 15, 2022, we had received full approval of a study (the **"UK Trial"**) in the United Kingdom from the UK Medicines and Healthcare products Regulatory Agency (**"MHRA"**) using natural psilocybin in the field of palliative care with oncology patients. For this study, we had partnered with Clerkenwell Clinics Limited (**"Clerkenwell Health"**), which would have been responsible for jointly designing and delivering the UK Trial. Following such approval, we opted to forego proceeding with the UK Trial in order to pursue the opportunity to conduct the Palliative Care Clinical Trial in Australia, as Psyence could benefit from the Australian Federal Government's Research & Development tax incentive program, which could provide up to a 43.5% rebate on Psyence's research and development expenses in Australia, making it a more cost-effective endeavor. In addition, the Palliative Care Clinical Trial adds a dose-finding arm, which allows us to accelerate our development strategy by seeking input from the FDA through a consultation program during our pre-IND application.

On October 10, 2023 responses to the initial Human Research Ethics Committee review were submitted. Full approval of the Palliative Care Clinical Trial as a Phase IIb study is expected in Q4 2023. Preparations for the initiation of the Phase IIb study in Australia are in the final stages.

# **Psyence Production**

Psyence has built and operates one of the first federally licensed commercial psilocybin cultivation and production facilities in the world, the Psyence Production Facility. We are focused on the production of certified, pharmaceutical-quality psilocybin - yielding mushrooms. The Psyence Production Facility, which is situated in Lesotho, Southern Africa, has been designed and constructed to The British Standards Institute (**"BSI"**) and Good Manufacturing Practice (**"GMP"**) standards. It is equipped with technology and specialized equipment to ensure optimum growing conditions and efficient harvesting and packaging.

The first successful harvest was completed in January 2021. Before commencing its final validation runs for BSI certification, the Company upgraded the facility by installing an automated heating, ventilation, and air conditioning (HVAC) system. This improved its production yield, giving the facility better climate control parameters. Psyence Production completed its first official validated harvest of psychedelic mushrooms and was audited by the BSI against ISO22000 standards in December 2021. The facility and team successfully passed the audits and received full ISO22000 certification in February 2022.

The Company exported products from the Psyence Production Facility using the Mind Health Lesotho Permit, coupled with an export permit from the Ministry of Health (Lesotho) as well as an import permit from the importing research partner's country's regulators. An experienced pharmaceutical export courier was selected after a prudent due diligence review process.

We received import permits from Health Canada on behalf of Psilo Scientific (a subsidiary of Filament). The Company also received import permits from the Portuguese regulators for the Cooperativa de Ensino Superior Politécnico e Universitário (CESPU) in Portugal. The export of product to our research partners was to analyse our mushrooms and develop extraction methods and potentially used in clinical trials. The exports to Canada, Portugal and the UK were completed efficiently. No material sales of the products from the Psyence Production Facility have occurred to date. The exports were completed in July 2022.

Several upgrades to the Psyence Production Facility have been completed, including an overarching roof structure that covers the entire campus of buildings that will create improved environmental



conditions and decrease contamination risk, as well as provide a better working environment for our staff.

We have also constructed a laboratory that has the ability to produce crude extracts from our mushrooms, perform in-process testing, generate certificates of analysis, cleaning validation and provide the ability to develop and refine the strains we grow. This enables the Company to save costs, speed up testing time and provide customers with a standardised processed product.

Our crude extract has been exported to a contract manufacturing partner in the UK who is in the process of developing methodologies to produce a GMP complaint, pharmaceutical grade, psilocybin-containing active pharmaceutical ingredient (**"API"**).

As a result of the facility upgrades, new laboratory and laboratory equipment, we have increased our production capacity and are seeing improving yields.

We received an investment in order to expand our extraction capabilities to isolate and stabilise psilocybin and psilocin extracts. The equipment to be used to further our extraction activities has been ordered and prepaid.

The Psyence production facility is being upgraded with the new extraction equipment manufactured by Eden Labs LLC (**"Eden"**).

The upgrade will enable Psyence to have the capability to undertake further extraction at the facility, using Psyence's natural psilocybin mushrooms, which will be processed into a crude extract stabilized powder format. Psyence's extraction partners and CROs will then process this stabilized input material into an API. There are multiple potential benefits to an on-site extraction including increased product shelf life, more stabilized format for export, and reduced transport costs.

The equipment supplied by Eden was shipped from the USA and arrived on site in October 2023. Construction has commenced on the rooms to house the extraction equipment and is expected to be completed and commissioned by the end of Q4 2023

# **Relationships with Third Parties**

The Company's Australian-based research and development will be conducted by its licensed partner, and its CRO partner, iNGENū, in Australia. As stated above, Filament's PEX010 will serve as the drug candidate under investigation during the Palliative Care Clinical Trial being conducted in Australia.

The Company's UK-based research and development was to be conducted by way of its licensed partner, and its CRO partner, Clerkenwell Health, in the UK, however we opted to intentionally pause proceeding with the UK Trial in order to focus on the Palliative Care Clinical Trial.

The Company terminated the management service agreement ("Highlands MSA") with Highlands Ventures (Pty) Ltd ("Highlands Ventures") effectively from April 1, 2023. Limited aspects of the operation of the Psyence Production Facility (country manager and government relations for example) were dependent Highlands Ventures, the terms of which are set out in more detail below in *Transactions between Related Parties - Other Related Party Transactions*.

The Psyence Production Facility is located on land which is sub-let by Mind Health Lesotho from Highlands Pure Lesotho (Pty) Ltd ("Highlands Pure Lesotho"). Accordingly, the continued validity of Highlands Pure Lesotho's rights to sub-let such land is crucial to the Company's ongoing business operations in the region. The Company has mitigated such risks through the inclusion of "step-in" rights in favour of Mind Health Lesotho whereby it may step in and act on Highlands Pure Lesotho's behalf (i) to remedy any breaches of contract, (ii) make any payment due by Highlands Pure Lesotho under the main lease and/or (iii) renew the main lease, and ultimately take transfer of all of Highlands Pure Lesotho's rights and obligations under such main lease.



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

# Update on Significant Milestones and Business Objectives

The below table is intended to provide an update, as at September 30, 2023 on the Company's business objectives and milestones as disclosed in the Company's Listing Statement dated January 25, 2021 ("Listing Statement"). As at September 30, 2023, the Company provides below the status of these milestones, the actual or revised estimated costs and the revised date of expected completion thereof, if applicable. Further, the Company has included additional objectives and milestones that have been identified since the date of the Listing Statement.

The following are "forward-looking statements" and accordingly, there is no guarantee that such milestones will be achieved on the timelines indicated, or at all. All milestones and business objectives are subject to the regulations and laws governing the jurisdictions in which Psyence operates. Forward-looking statements are based on management's current expectations and are subject to a number of risks, uncertainties, and assumptions. Please refer to "*Forward-Looking Information*" above and "*Risk Factors*" below for more information.

Objective	Milestones <sup>(1)</sup>	Prior Estimated Cost in Listing Statement <sup>(2)</sup>	Actual or Revised Estimated Cost (January 25, 2021 to September 30, 2023)	Actual/ Estimated Timeframe for Completion <sup>(3)</sup>	Status
	Capital Expenditure Phase 1.	\$100,000	\$105,168	Q2 2021	Completed
Psyence Production (Cultivation and Production)	Commencing of cultivation including first harvest, sourcing of spores and hiring of mycologist and microbiologist. <sup>(4)</sup>	\$20,500	\$19,015	Q1 2021 and Q2 2021	Completed
i roudotion,	First export <sup>(5)</sup>	\$40,000	\$14,270	Q3 2022	Completed
	Ongoing cultivation and production expenditure <sup>(6)</sup>	\$70,500	\$297,648	Ongoing	Ongoing
	Scale up of Production Facility. <sup>(7)</sup>	Nil	\$150,978	Q2 2022	Completed
Psyence	Data collection from 3 <sup>rd</sup> party patient cohorts. <sup>(8)</sup>	\$360,000	Nil	Q1 2022	Cancelled
Therapeutics (Observational	Observational studies at Lesotho.	\$361,000	Nil	N/A	Cancelled
Studies)	Observational studies of Animal Seizure Model. <sup>(9)</sup>	Nil	\$16,205	Q1 2023	Completed
Psyence	Hiring of product development specialist. <sup>(10)</sup>	\$85,000	\$54,708	N/A	Cancelled
Therapeutics and Psyence	Engage consultants to develop slow-release product. <sup>(11)</sup>	\$130,000	\$28,471	Q4 2021	Cancelled
Function (Product	Development of formulation.	\$137,000	Nil	N/A	Cancelled
Development)	Commence clinical observational studies. <sup>(12)</sup>	\$713,000	Nil	N/A	Cancelled



	Launch of functional mushroom brand, "GOODMIND". <sup>(13)</sup>	Nil	\$330,458	Q2 2022	Completed
Psyence Therapeutics (Scientific Research and Clinical Trials)	Collaboration Agreement with SRC Phase 1, 2 and 3: Product and Protocol development, collection and storage of mushroom strains. <sup>(14)</sup>	Nil	\$85,500	N/A	Ceased
	Finalize JV with Pure Extracts Technologies Corp.	Nil	\$2,000	Q2 2021	Completed
Psyence Therapeutics (Extraction of Psilocybin and Research)	Pure Extracts Technologies Corp. will facilitate the importation of psychedelic mushrooms into Canada.	Nil	N/A	N/A	Ceased
	Partnership Agreement with Eden for extraction and product development. <sup>(15)</sup>	Nil	\$1,207,821	Q4 2023	In progress
	Partnership agreement with Clerkenwell Health to jointly design UK clinical trials. <sup>(16)</sup>	Nil	\$267,457	Q2 2022	Completed
	Licensing agreement with Filament Health Corp. <sup>(17)</sup>	Nil	\$250,000	Q2 2022 and Q3 2023	Completed
	Product development with a Contract Development & Manufacturing Partner. <sup>(18)</sup>	Nil	\$97,874	To be determined	On track
Psyence Therapeutics (Clinical Trials)	LOI with iNGENu to jointly design and deliver Phase IIb clinical trials in Australia. <sup>(19)</sup>	Nil	\$ 114,354	Q1 2023	Completed
	iNGENū MSA signed with iNGENu to jointly design and deliver Nil Phase IIb clinical trials in Australia. <sup>(20)</sup>	Nil	\$7,476,983	Q4 2024	On track
	Business combination between wholly owned subsidiary Psyence Biomed Corp. and Nasdaq listed Newcourt Acquisition Corp. <sup>(21)</sup>	Nil	\$817,858	To be determined	In progress
	TOTAL	\$2,017,000	\$11,336,767		

# Notes:

- (1) There may be sound business reasons underlying the Company's decision to reallocate funds or not to proceed with a milestone.
- (2) These were, and still are, subject to receipt of necessary approvals, including the academic and scientific organizations (2) Index with and the data and, call botton in with which the Company is working.(3) Based on a calendar year-end.
- (4) The Company concluded its first cultivation and harvest cycle of natural medical psilocybin mushrooms in January 2021. The Company hired a mycologist who started in May 2021.



- (5) The Company received an import permit for raw psilocybin material from Health Canada on behalf of Psilo Scientific and from the Portuguese regulators on behalf of Cooperativa de Ensino Superior Politécnico e Universitário (CESPU) in Portugal. The export took place in August 2022 after the Company secured an export permit from Lesotho. The Company has ceased business activities in Jamaica and has exported products to Canada, Portugal and the UK.
- (6) This includes work performed to achieve BSI certification as well as ongoing annual fees. The annual fees are ZAR80,000 (eighty thousand South African Rands).
- (7) The Company expanded its laboratory facility in Lesotho and added an overarching roof structure to cover the operations area. Construction work was completed in Q2 2022.
- (8) The Company had entered into a Research Collaboration Agreement with MycoMeditations Inc. for research and development based observational studies that have been completed. This project was cancelled due to the realignment of the Company's strategy.
- (9) The Company had entered into a Research Collaboration Agreement with the University of Toronto for research and development based observational studies of the effects of psilocybin in an Animal Seizure Model. The cost was \$16,205.
- (10) A service level agreement was entered into with Singapore-based medical biology, forensic science and product development company Base Pair Global Pte. Ltd ("BPH"). BPH completed the evaluation of the development of nutritional products and the Company concluded that it would not proceed with the program in order to prioritize the launch of the functional mushroom brand, GOODMIND<sup>™</sup>. The agreement with BPH was terminated in August 2021 by way of mutual agreement.
- (11) The Company entered a 3-month agreement with a consultant in August 2021 to start September 1, 2021, initially to develop the slow-release product with BPH, however the Company decided to prioritize the development and marketing of GOODMIND<sup>™</sup>.
- (12) The Company revised its strategy to allocate resources and funds to its Palliative Care Clinical Trial.
- (13) The Company entered a 50/50 joint venture through a South African-based special purpose vehicle, Good Psyence. The Company launched its functional mushroom brand, GOODMIND<sup>™</sup>, through Good Psyence in August 2021. The product was launched in the UK in Q4 2022.
- (14) As mentioned in note 5, the Company has ceased business activities in Jamaica.
- (15) The Company entered a partnership agreement with Eden. The partnership features a Global IP Licencing Agreement (the salient terms of which have been agreed) for the commercialization by the Company for the extraction technology and formulation IP developed by Eden to produce a water soluble, doseable, stabilized psilocybin powder naturally derived from the fruiting bodies of psilocybin-yielding mushrooms cultivated and processed at the federally licensed certified facility in Southern Africa. The specific terms of this Global IP Licencing Agreement are planned to be finalised prior to project completion. The cost is estimated at \$1,207,821 for the extraction machine.
- (16) The Company and Clerkenwell Health were responsible for jointly designing UK clinical trials. Clerkenwell Health assisted the Company in establishing procedures and protocols required to successfully run a clinical trial and gain regulatory approval for the Company's envisaged psilocybin-containing product range. The cost was \$267,457.
- (17) The Company had entered into an exclusive licencing agreement with Filament Health for the development of natural psilocybin products in respect of phase II clinical trials as well as an exclusive licencing agreement for the commercialisation of such products in respect of the phase III and commercialisation phase of drug development. The cost is estimated at \$250,000.
- (18) The Company has partnered with a Contract Development and Manufacturing Partner in the UK for the development of standardised pharmaceutical grade psilocybin and psilocin extracts. The cost is estimated at \$97,874.
- (19) The Company signed a Letter of Intent with Australian CRO iNGENu to execute the clinical development of psilocybin within palliative care. The LOI centres around the Company's global development and regulatory strategy of its licensed compound PEX010 in palliative care in Phase II clinical trials.
- (20) The Company signed a Master Services Agreement with Australian CRO iNGENu to execute the clinical development of psilocybin within palliative care. The commencement, regulatory services and site selection have been completed. The cost for the clinical trial is estimated to be \$7,476,983.

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

#### Update on Use of Proceeds

The Company has committed the following capital expenditures to meet its planned growth and fund development activities as of September 30, 2023, and the Company does not anticipate, any changes to its previously made disclosure about the Company's intended use of proceeds except as described below.

The below table below sets out the anticipated use of the available funds and any variances to such use as described in the Listing Statement, and the Company's actual use of proceeds from financings



and a private placement as at September 30, 2023. The current use of funds represents the total of the underspend/overspend. The Company notes that the below variances are not expected to have a material impact on the Company's ability to achieve its business objectives and milestones.

Use of Avail		Previous disclosure regarding use of proceeds in Listing Statement	Actual use of Proceeds as at September 30, 2023 (January 25, 2021 – September 30, 2023)	Additional amounts allocated/(redistribut ed) at September 30, 2023	Current use of proceeds (April 1, 2023 – September 30, 2024
	Capital Expenditure Phase 1	\$100,000	\$105,169	\$5,169	Nil
Psyence Production (Cultivation and	Commencing of cultivation including first harvest, sourcing of spores and hiring of mycologist and microbiologist	\$20,500	\$19,015	(\$1,485)	Nil
Production) <sup>(1)</sup>	First export	\$40,000	\$14,270	(\$25,730)	Nil
,	Ongoing cultivation and production expenditure	\$70,500	\$352,665	\$282,165	Nil
	Scale up of Production Facility	Nil	\$150,978	\$150,978	Nil
_	Data collection from 3 <sup>rd</sup> party patient cohorts	\$360,000	\$70,000	(\$290,000)	Nil
Psyence Therapeutics (Observation	Observational studies at Lesotho clinic	\$361,000	Nil	(\$361,000)	Nil
al Studies) <sup>(2)</sup>	Observational studies of Animal Seizure Model	Nil	\$16,205	\$16,205	Nil
	Hiring of product development specialist	\$85,000	\$54,708	(\$30,292)	Nil
Psyence Therapeutics and Psyence	Engage consultants to develop slow- release product	\$130,000	\$28,471	(\$101,529)	Nil
Function	Development of formulation	\$137,000	Nil	(\$137,000)	Nil
(Product Development) (3)	Commence clinical observational studies	\$713,000	Nil	(\$713,000)	Nil
	Launch of functional mushroom brand, "GOODMIND"	Nil	\$267,581	\$Nil	\$267,581
	Finalize Joint Venture with	Nil	\$2,000	(\$2,000)	Nil



	1				
	Pure Extracts				
Psyence	Technologies				
Therapeutics	Corp. <sup>(4)</sup>				
(Extraction of	Partnership				
	Agreement				
Psilocybin	with Eden for				<b>*</b> • • • • • •
and	extraction and	Nil	\$851,549	\$1,207,821	\$356,273
Research)	product				
···· ,	development <sup>(5)</sup>				
	Collaboration				
Psyence Therapeutics (Clinical Trials) <sup>(5)</sup>	Agreement with SRC Phase 1, 2 and 3: Product and Protocol development, collection and storage of mushroom strains	Nil	Nil	Nil	Nil
	Partnership agreement with Clerkenwell Health to jointly design and deliver UK clinical trials <sup>(6)</sup>	Nil	\$267,457	\$267,457	Nil
	Licensing agreement with Filament Health Corp <sup>(7)</sup>	Nil	\$225,000	\$250,000	\$25,000
	Product development with a Contract Development & Manufacturing Partner	Nil	Nil	\$97,874	\$97,874
Psyence Therapeutics (Clinical Trials)	LOI with Australian CRO iNGENu to jointly design and deliver AUS Phase IIb clinical trials.	Nil	\$105,618	\$114,354	\$8,736
	Master Service Agreement signed with iNGENu to jointly design and deliver Phase IIb clinical trials in Australia.	Nil	\$2,082,063	\$7,476,983	\$5,394,919
	Business combination between wholly owned subsidiary Psyence Biomed Corp. and Nasdaq listed	Nil	\$692,320	\$817,858	\$125,556



	Newcourt Acquisition Corp.				
	Professional and consulting fees	\$630,000	\$7,502,238,	\$7,600,000	\$727,762
	General and Administrative	\$901,219	\$2,197,366	\$2,500,000	\$1,203,853
Other	Investment from Private Placement <sup>(9)</sup>	Nil	(\$4,444,870)	(\$4,444,870)	Nil
	Total use of funds	\$3,548,219	\$10,559,803	\$14,679,976	\$8,207,554
	Unallocated working capital <sup>(10)</sup>	\$2,294,510	(\$4,717,074)		
TOTAL		\$5,842,729	\$5,842,729		

#### Notes:

- (1) The Company completed the capital expenditure on Phase 1 of the setting up of the laboratory and grow room. Additional costs of \$5,000 were spent on upgrading the grow room. The Company finished the cultivation and first harvest within the budget. The Company sourced a new mycologist during the first quarter of 2021. This change led to a change in cultivation methods and therefore the overspend on ongoing cultivation.
- (2) The Company entered into a Research Collaboration Agreement with MycoMeditations Inc. for research and development based observational studies that have been completed. The actual spend for the period was \$70,000. This project was cancelled due to the realignment of the Company's strategy. In a separate initiative, the Company no longer anticipates conducting observational studies in Lesotho.
- (3) The Company revised its strategy and allocated resources and focus to its Palliative Care Clinical Trial. The Company entered a 50/50 partnership through a South African-based special purpose vehicle, Good Psyence. The Company launched its functional mushroom brand, GOODMIND<sup>™</sup>, through Good Psyence in August 2021. The product was launched in the UK in Q4 2022. The actual costs spend during the period was \$267,581.
- (4) The Company finalized the set-up of the joint venture with Pure Extracts Technologies Corp. The costs spend to setup Pure Psyence Corp. was \$2,000. The joint venture has not had any activity to date and is in the process of being dissolved.
- (5) The Company entered a partnership agreement with Eden. The partnership features a Global IP Licencing Agreement (the salient terms of which have been agreed) for the commercialization by the Company for the extraction technology and formulation IP developed by Eden to produce a water soluble, doseable, stabilized psilocybin powder naturally derived from the fruiting bodies of psilocybin-yielding mushrooms cultivated and processed at the federally licensed certified facility in Southern Africa. The specific terms of this Global IP Licencing Agreement are planned to be finalised prior to project completion. The cost is estimated at \$1,207,821 for the extraction machinery.
- (6) The Company and Clerkenwell Health were responsible for jointly designing and delivering UK clinical trials. Clerkenwell Health assisted the Company in establishing procedures and protocols required to successfully run a clinical trial to gain regulatory approval for the Company's envisaged psilocybin-containing product range. The actual cost spend was \$267,457.
- (7) The Company has ceased business activities in Jamaica and exported products to Canada, UK and Portugal. The Company has entered into a licensing agreement with Filament who will license its proprietary botanical drug candidate PEX010 (25mg), and the associated intellectual property for Psyence to use in the upcoming clinical trials.
- (8) General and administrative expenses are comprised of payroll consulting and benefits of \$996,964; office and administrative costs of \$790,482; sales and marketing investor relations costs of \$409,110.
- (9) Closing of third tranche of private placement of up to \$4.4 million.
- (10) If there is any unallocated working capital balance, it will be held in short-term interest-bearing securities or in bank accounts at the discretion of management.

The Company has negative cash flow from operating activities and has historically incurred net losses. To the extent that the Company has negative operating cash flows in future periods, it may need to deploy a portion of its existing available cash to fund such negative cash flows. The expected use of funds represents the Company's current intentions based upon its present plans and business condition, which could change in the future as its plans and business conditions evolve. The amounts and timing of the actual use of the net proceeds depends on multiple factors and there may be



circumstances where, for sound business reasons, a reallocation of funds may be necessary in order for the Company to achieve its stated business objectives. The Company may also require additional funds in order to fulfil its expenditure requirements to meet existing and any new business objectives, and the Company expects to issue additional securities or incur debt to do so. As a result, management retains broad discretion in the application of the available funds, and shareholders will be relying on the management's judgment regarding such application. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favourable to the Company as those previously obtained.

See "Quarterly Results of Operations" section for a discussion of transaction costs, marketing expenditure and general and administrative expenses.

## Intellectual Property

## Trademarks

The trademark "GOODMIND" is currently owned by Psyence's joint venture in South Africa, Good Psyence. The joint venture has applied to register the trademark "GOODMIND" in South Africa, UK, EU, USA, Canada and Australia.

The Company has filed applications for the registration of the Psyence<sup>™</sup> trademark in several jurisdictions including Canada, USA, UK, South Africa and Jamaica. Confirmation of registration of the Psyence<sup>™</sup> trademark has been received in respect of Jamaica and the UK. Furthermore, the Company has filed applications in Canada for the registration of several trademarks including LET PSYENCE LEAD THE WAY<sup>™</sup>, OPENING DOORS<sup>™</sup>, and QUALITY OF MIND<sup>™</sup>.

# **Clinical Trials**

The Company has a strong focus on the treatment of anxiety, particularly in the area of palliative care, and has partnered with Clerkenwell Health and iNGENū to initiate rigorous clinical trials to prove efficacy. The Company's objective is to develop a naturally derived, stable and standardized extract API which will lead to specific product formulations and delivery mechanisms suitable for such clinical trials. As the Company creates novel intellectual property and new data in this area, it may file appropriate patent applications at a more appropriate time in the future, as part of the Company's intellectual property development strategy.

# Licensed Intellectual Property

In April 2022, Psyence entered into an agreement with Filament for the licensing of PEX010 and its associated intellectual property, as well as for the supply of PEX010 for the specific intention of the clinical development of the product, and ultimately, for the marketing authorization for PEX010's use in palliative care patients. PEX010 will serve as the drug candidate under investigation during the Palliative Care Clinical Trial. This license, granted in respect of the clinical trial phase of Psyence's activities, applies worldwide, but is exclusively licensed to Psyence in the UK within the field of use being anxiety and depression, including associated ailments, such as PTSD, stress, grief, and AjD within the context of palliative care. Pursuant to the license, Psyence will own all the data, results of testing, research, any information and any other IP derived or arising from any clinical trials, with the exclusion of IP related to the manufacture, processing or production of the Filament input material, which will vest in Filament.

In December 2022, Psyence further secured royalty-bearing, worldwide commercial licensing rights from Filament, which grants Psyence the worldwide right to commercialize PEX010 within the context of palliative care. Such commercialization rights are exclusively granted to Psyence in the UK, EU, and US and, Psyence has a right of first refusal to extend its exclusive license beyond such territories, including to Australia. The aforementioned agreements shall collectively be referred to as the **"Filament Licensing Agreements"**.



The Company has entered into a partnership with Eden as a product development and extraction technology company that has developed certain extraction intellectual property and methodologies. The partnership involves the purchasing of certain machinery from Eden and features the global licensing of processing intellectual property so that Psyence may refine its product development activities and improve its production and product offerings. The specific terms of this global IP licencing agreement will be finalised at a later stage when the need and scope of the licensed IP becomes clearer.

# **Regulatory Framework and Licensing Regime**

A summary of the applicable regulatory framework for the Company's various business segments and proposed business activity is set out in the table below.

Business Segment	Current / Proposed Jurisdiction of Operation	Summary of Applicable Regulatory Frameworks	Third-party CROs, Suppliers, and/or Manufacturers	Related Agreements/ Contracts⁵
Psyence Production – Psyence Production Facility	Lesotho	<ul> <li>Drugs of Abuse Act 5 of 2008 (Lesotho)</li> <li>and international narcotics laws:</li> <li>The Single Convention on Narcotic Drugs done at New York on 30 March 1961, as amended by the 1972 Protocol amending the Single Convention done at Geneva on 1972</li> <li>The Convention Against Psychotropic Substance done at Vienna on 21 February 1971</li> <li>The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances done at Vienna on 20 December 1988<sup>1</sup></li> </ul>	<ul> <li>Clerkenwell Health</li> <li>Filament</li> <li>Eden</li> </ul>	<ul> <li>Clinical and Non-Clinical Services Agreement concluded with Clerkenwell Health</li> <li>Filament Licensing Agreements</li> <li>Extraction Project Heads of Terms and Global IP Licensing Agreement (under finalisation)</li> </ul>
Psyence Therapeutics – Research and Development and Clinical Trials	UK, Canada and Australia	<ul> <li>UK:</li> <li>1971 UN Convention on Psychotropic Substances</li> <li>Misuse of Drugs Act 1971 and Regulations 2001</li> <li>Psychoactive Substances Act 2016</li> <li>Human Medicines Regulations 2012<sup>2</sup></li> <li>Canada:</li> <li>Controlled Drugs and Substances Act</li> <li>Food and Drugs Act, R.S.C. 1985, c. F-27, and the Food and Drug Regulations thereunder, C.R.C., c. 870<sup>3</sup></li> <li>Australia:</li> <li>The Therapeutic Goods Act 1989</li> <li>Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023</li> <li>Customs (Prohibited Imports) Regulations 1956<sup>4</sup></li> </ul>	<ul> <li>Clerkenwell Health</li> <li>Filament</li> <li>iNGENū</li> </ul>	<ul> <li>Clinical and Non-Clinical Services Agreement concluded with Clerkenwell Health</li> <li>Filament Licensing Agreements</li> <li>iNGENū MSA</li> </ul>
Psyence Function – GOODMIND <sup>™</sup>	South Africa and UK	South Africa: • Foodstuffs, Cosmetics and Disinfectant Act, No 54 of 1972 • Medicines and Related Substances Control Act 101 of 1965 <sup>5</sup> UK: Food supplements are regulated by legislation made in each part of the UK. This legislative framework is still under investigation.	<ul> <li>Goodleaf</li> <li>Good Psyence</li> <li>Mycotrition GmbH</li> </ul>	<ul> <li>Joint venture and shareholder agreement</li> <li>Subscription and Intellectual Property Agreement</li> <li>Supply Agreement</li> </ul>

Notes:

(1) From more information on the regulatory regime in Lesotho, please refer to "Lesotho" below.

(2) From more information on the regulatory regime in the UK, please refer to "United Kingdom" below.



- (3) From more information on the regulatory regime in Canada, please refer to "Canada" below.
- (4) From more information on the regulatory regime in South Africa, please refer to "South Africa" below.
- (5) From more information on the regulatory regime in Australia, please refer to "Australia" below.

# (6) For more information regarding contracts related to the operations of the Company, please refer to "Material Contracts" below.

#### Lesotho

Mind Health Lesotho has been issued a licence to engage in trade and/or manufacture by the Ministry of Trade and Industry, Cooperatives and Marketing (Lesotho), in terms of the Industrial Licensing Act 1969 and Trading Enterprises Act 1993, which licence has been properly and duly renewed.

The business activities in which Mind Health Lesotho currently engages is the growing, harvesting, storage and exportation of psilocybin containing mushrooms for medical and research purposes only ("Lesotho Activities"). Currently, Mind Health Lesotho only deals in raw materials in mushroom format, however upgrades and improvements to the Psyence Production Facility located in Kolojane, Lesotho creates the opportunity for Mind Health Lesotho to expand its activities. The Lesotho Activities are conducted in accordance with the Mind Health Lesotho Permit. This permit authorizes Mind Health Lesotho to conduct the following activities: (a) cultivation of psilocybin; (b) importation of starting material for cultivation of psilocybin; (c) production and manufacture of psilocybin or forms thereof as an API (active pharmaceutical ingredient); (d) exportation of psilocybin, in all forms, to medicinal and pharmaceutical companies; and (e) importation of psilocybin in all forms. The minimum standards to be complied with include, among others, that: (a) activities conducted are for medical purposes only; (b) a qualified responsible pharmacist is present on site; (c) access control is in place; (d) temperature and humidity-controlled production environments and storage facilities are provided for; (f) an HVAC system will include high-efficiency particulate air (HEPA) filters; and (g) in the event of agricultural activities occurring within the Psyence Production Facility, that good agricultural practices are adhered to. The Mind Health Lesotho Permit expressly identifies the Psyence Production Facility located in Kolojane, Lesotho as the authorized premises to carry out the Lesotho Activities. The Mind Health Lesotho Permit was granted for a ten-year period, which is automatically renewable thereafter, provided that the Minister of Health (Lesotho) is satisfied that Mind Health Lesotho has conducted its activities in compliance with the permit and remains compliant upon the date of renewal.

The Lesotho Activities (and the regulation of controlled substances in general) are governed by the following pieces of legislation and applicable laws: (a) Drugs of Abuse Act 5 of 2008 ("DAA"); (b) Legal Notice: Appointment of the Lesotho Narcotics Bureau No. 86 of 2017; (c) The Single Convention on Narcotic Drugs done at New York on 30 March 1961 ("1961 Convention"), as amended by the 1972 Protocol amending the Single Convention done at Geneva on 1972 ("1972 Protocol"); (d) The Convention Against Psychotropic Substance done at Vienna on 21 February 1971 ("1971 Convention") and; (e) The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances done at Vienna on 20 December 1988 ("1988 Convention").

The DAA was promulgated to govern and regulate controlled substances, issue licences and permits in respect of the activities involving controlled substances and establish the Lesotho Narcotics Bureau ("LNB"), among other things. The LNB is responsible for all duties of the National Narcotics Agency provided for under the 1961 Convention, advises the Minister of Health (Lesotho) on policy development and implementation with regard to illicit drugs and drug traffickers and co-ordinates all drug abuse related activities of government ministries, departments and non-governmental organisations aimed at illicit drug trafficking. Lesotho is a signatory to the following international conventions relating to narcotics and psychotropic substances: (a) the 1961 Convention and 1972 Protocol; (b) the 1971 Convention; and (c) the 1988 Convention. Lesotho has ratified the contents of the aforementioned international laws through the enactment of the DAA. In terms of the DAA, with reference to Schedule 1 as referred to in section 4(2) of the Act, psilocin and psilocybin are prohibited substances. This is aligned with Schedule 1 of the 1971 Convention where the active pharmaceutical ingredients psilocin and psilocybin are expressly prohibited. Article 2(9) of the 1971 Convention states that:

"the parties shall use their best endeavours to apply to substances which do not fall under this Convention, but which may be used in the illicit manufacture of psychotropic substances, such measures of supervision as may be practicable"



Accordingly, the appropriate discretion is given to a member state and or its delegates (in this case the Minister of Health (Lesotho)) in terms of the 1971 Convention to promulgate legislation, issue regulations or otherwise exercise the appropriate statutory powers if, in the member's opinion, a substance is necessary for medicinal purposes. The Minister of Health (Lesotho) is empowered under the DAA to ensure compliance the 1971 Convention and the recommendations of International Narcotics Control Board by exercising supervision and control over plants which may be used to manufacture a psychotropic substance (such as psilocybin). The DAA provides for the delegation of power to the Minister of Health (Lesotho) to promulgate regulations to regulate controlled substances as he deems necessary if he is of the opinion that same is necessary for medical or scientific purposes.

Section 9(4) of the DAA provides that no person who carries on a business of the manufacture, acquisition or supply of a drug of abuse, intended for medical, scientific use or other lawful use (referred to as an **"operator"**) shall, among other things, acquire, possess or export a drug of abuse except pursuant to a licence issued by the Minister of Health (Lesotho). An operator who is required by the DAA to be licensed shall apply in writing to the Minister of Health (Lesotho) for the granting of such a licence. The Minister may grant the licence if he/she is satisfied that the activity will be carried out exclusively for medical or scientific purposes. The LNB assists the Minister of Health (Lesotho) in assessing applications submitted for such operator licenses. In the event of the importation or exportation of a controlled substance, an application for the requisite import, export or transit permit must be made under section 14 of the DAA and such import, export or transit permit may be granted by the Minister of Health (Lesotho) pursuant to section 15 of the Act.

The DAA comprehensively sets out the administration, compliance and enforcement of its provisions in Part V of the Act. As stated above, the LNB is tasked with assisting the Lesotho Government in implementing the abovementioned UN drug conventions and the SADC Protocol on combating drugs and illicit drug trafficking. The DAA further regulates and empowers the Minister of Health (Lesotho), the LNB and/or their appointees to conduct compliance and enforcement measure as follows: (a) inspection for compliance (Division 2); (b) investigation of offences (Division 3); and (c) seizure and post seizure procedures (Division 4). Failure to comply with the provisions of the DAA is an offence, punishable by law and can result in the suspension or revocation of licences and permits issued thereunder.

# Jamaica

The Company has ceased its activities in Jamaica, specifically the research collaboration with the SRC, an agency of the government of Jamaica with respect to a Research and Collaboration Agreement pursuant to which the parties intended commencing a research project entitled "*Collection, Cultivation, Characterization and Product Development of Psilocybin Containing Mushrooms*". The aforementioned Project (now terminated) was the sole, active business activity in which Psyence Jamaica was engaged. The Company has filed a request for Psyence Jamaica to be removed from the list of registered companies appearing on the company register with the Companies Office of Jamaica. The Company anticipates conducting future product development in the UK, Australia and Canada in line with future clinical trials.

# South Africa

PBC entered into a joint venture with Goodleaf to launch a functional mushroom product under the name "GOODMIND" in South Africa, which products would be owned by and traded through Good Psyence.

The GOODMIND<sup>™</sup> products contain a range of functional/nutritional mushrooms including reishi, cordyceps CS-4 and lion's mane extracts as well as agaricus blazei, coriolus, Auricularia, shiitake and chaga. The products do not contain any psilocybin or any other controlled substance under the narcotics laws in South Africa. Online commercial sales of the products commenced in South Africa in calendar Q4 2021 and remain ongoing.

The GOODMIND<sup>™</sup> products are governed by: (a) Foodstuffs, Cosmetics and Disinfectant Act, No 54 of 1972 (**"Foodstuffs Act"**); (b) Medicines and Related Substances Control Act 101 of 1965



("Medicines Act"); and (c) all notices and regulations issued in accordance with the aforementioned Acts.

# Foodstuffs

The Foodstuffs Act regulates and controls the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants and provides for incidental matters. The enforcement of this Act is overseen by the Minister of Health (South Africa) and the inspectors appointed by the Director-General in the Department of Health (South Africa). No person may manufacture, import, sell or offer any foodstuff for sale, unless it complies with the Foodstuffs Act and the regulations thereto. No licences are required to be issued under the Foodstuffs Act to launch the GOODMIND<sup>™</sup> products and these products may therefore be sold in an open shop. Provided that the products meet the quality, safety, labelling, packaging and other requirements set out in the Foodstuffs Act and its accompanying regulations, the products shall be lawful in South Africa.

# Health supplements and complementary medicines

The Medicines Act provides for, *inter alia*, the registration of medicines and related substances intended for human and for animal use, the control of medicines and scheduled substances and medical devices and the regulation of the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines. This Act established The South African Health Products Regulatory Authority (**"SAHPRA"**) as an organ of state within the public administration but outside the public service. The enforcement and management of this Act is overseen by the Minister of Health (South Africa), with the support of SAHPRA and the Director-General in the Department of Health.

The Company has determined that the classification of GOODMIND<sup>™</sup> products as a foodstuff is more appropriate than the classifications of "complementary medicines" or "health supplements" as defined in the Medicines Act. Accordingly, the GOODMIND<sup>™</sup> products do not require any registrations under the Medicines Act and have not been evaluated by SAHPRA for its quality, safety or intended use.

Health supplements are regulated in accordance with guidelines issued by SAHPRA titled "Registration of Medicines: CMs Health Supplements – Safety and Efficacy June 2020" which sets out standards to ensure that products sold to the public are of good quality and are safe. In this regard, reference is made to the "Roadmap and transitional process for the regulation of complementary medicines" issued by SAHPRA ("**Roadmap**"). This document establishes the roadmap and general overview for the regulatory pathway of complementary medicines including licensing in terms of section 22C(1)(b) of the Medicines Act and submission of applications for their registration following the implementation of the General Regulations in 2017 and applies to products for human consumption (discipline-specific medicines and health supplements).

No call-up notices for registration have been issued in respect of the GOODMIND<sup>™</sup> products, nor are any such call-up notices anticipated, however should such call-up notices be received, Good Psyence will be required to follow the registration process set out in the Roadmap and adhere to the deadlines imposed by SAHPRA.

# Online sales

As stated above the GOODMIND<sup>TM</sup> products may be sold in an open shop. The online sales of GOODMIND<sup>TM</sup> products are subject to consumer protection and information privacy laws. The Consumer Protection Act, No. 68 of 2006 (**"CPA"**) is the legislative instrument governing liability in respect of defective or unsafe goods and general consumer protection. The Act provides for certain fundamental consumer rights, including: a) the consumer's rights to privacy; b) the right disclosure and information; c) the right to fair and responsible marketing; d) the right to fair and honest dealing; e) the right to fair, just and reasonable terms and conditions; f) the right to fair value, good quality and safety; and g) a supplier's accountability to consumers.



The Protection of Personal Information Act, No 4. of 2013 (**"POPI Act"**) is akin to the EU's General Data Protection Regulation 2016/679 and places obligations upon responsible parties (called controllers in other jurisdictions) to lawfully process the personal information of data subjects (both natural and juristic persons). Online sales must ensure that the provisions of the POPI Act are adhered to.

# Canada

The Canadian Controlled Drugs and Substances Act ("CDSA") generally prohibits all uses of controlled substances and makes it an offence to possess, produce, sell, traffic, import or export a substance including psilocin or psilocybin. However, these prohibitions are subject to exceptions, in particular an exemption for a medical or scientific purpose, such as research or clinical trials, pursuant to subsection 56(1) of the CDSA. An application must be submitted to Health Canada in order to receive such an exemption. Other than the joint venture formed with Pure Extracts, Pure Psyence (currently in the process of being wound-up), the Company has not commenced psilocybin related commercial business activities in Canada. The Company has entered into a Sponsored Research and Collaboration Agreement with a duly licensed academic institution to conduct a research project featuring animals. The Company is in the process of facilitating the procurement of controlled materials required for the aforementioned project from a duly licensed supplier thereof. At all times, the Company will enter into partnerships with organisations which have obtained the necessary dealer's licence and/or section 56 exemption required to handle psilocybin in Canada as it currently does not possess any such licenses.

In addition to the CDSA, the import and export of psilocin or psilocybin are regulated under the Food and Drugs Act and the Food and Drug Regulations. A dealer's licence for psilocin or psilocybin may be obtained under Part J of the Food and Drug Regulations. These laws are described in more detail below:

# <u>CDSA</u>

The CDSA is the critical piece of legislation applicable to psilocin, psilocybin, and other psychoactive substances in Canada. The criminal law power is the basis for this federal legislation regarding controlled drugs and substances. Both Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof as well as psilocybin are (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof are substances included in Schedule III of the CDSA.

# Food and Drugs

In addition to the CDSA, the federal Food and Drugs Act, R.S.C. 1985, c. F-27, and the Food and Drug Regulations thereunder, C.R.C., c. 870, regulate food and drugs in Canada. Both psilocin (3–[2– (dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof as well as psilocybin (3–[2– (dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof are restricted drugs included in the Schedule to which Part J of the Food and Drug Regulations is applicable.

# <u>Research</u>

If the research to be conducted involves a drug for human use that is to be tested in a clinical trial involving human subjects, then Division V of the Food and Drug Regulations would be the applicable federal law. In addition, if the research is to be conducted in British Columbia or another province in Canada, then the provincial laws of that province should also be consulted, such as those laws regarding the protection of personal health information.

#### Exemptions & Licences – CDSA and Food and Drug Regulations

As stated above, the CDSA generally prohibits all uses of controlled substances and makes it an offence to possess, produce, sell, traffic, import or export a substance included in Schedule III, including psilocin or psilocybin. However, these prohibitions are subject to exceptions, in particular an exemption for a medical or scientific purpose, such as research or clinical trials, pursuant to subsection 56(1) of the CDSA, as follows: in terms of section 56(1) the Minister may, on any terms and conditions that the



Minister considers necessary, exempt from the application of all or any of the provisions of this Act or the regulations any person or class of persons or any controlled substance or precursor or any class of either of them if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest. An application must be submitted to Health Canada in order to receive such an exemption.

A dealer's licence for psilocin or psilocybin may be obtained under Part J of the Food and Drug Regulations. An individual who ordinarily resides in Canada or a corporation with a head office or branch office in Canada is eligible to apply for a dealer's licence for permission to produce, assemble, sell, provide, transport, send, deliver, import or export psilocin or psilocybin as a licensed dealer. An Application for a Controlled Drugs and Substances Dealer's Licence must be submitted to the Office of Controlled Substances at Health Canada. In order to qualify as a licensed dealer, a party must meet all of the requirements mandated by Part J of the Food and Drug Regulations, including having staff that meet the qualifications for a senior person in charge and a qualified person in charge. A dealer's licence must be obtained for each site at which activities are to be conducted. The activities that the licensee may engage in are limited to the strict confines to the licence.

In addition to the dealer's licence, an application must be submitted, and a permit must be obtained from Health Canada before each import or export of a restricted drug such as psilocin or psilocybin by a licensed dealer. This allows the government to track every gram in the country.

# United Kingdom

The Company has entered into a services agreement with Clerkenwell Health, a private company located in England. Clerkenwell Health is a research focused consultancy providing bespoke psychedelic research. Under the terms of the service agreement, the parties intend to work together in connection with clinical trials and research associated with psilocybin.

In the United Kingdom, it is relevant to note that the term "psychedelics" has no legal meaning. Psilocybin and other drugs commonly referred to as "psychedelics" in modern society are subject to strict legal and regulatory requirements in the United Kingdom, as briefly summarized below.

#### UN Conventions

The objective of the UN Narcotics Conventions has been to establish an international framework for the control of psychoactive substances limiting their availability for medical and scientific purposes. The UN Conventions also promotes the establishment of criminal offences and penalties associated with the misuse of controlled drugs.

The 1971 UN Convention on Psychotropic Substances lists in schedule 1:

- Psilocine;
- psilotsin 3-[2-(Dimethylamino)ethyl]indol-4-ol;
- Psilocybine 3-[2-(Dimethylamino)ethyl]indol-4-yl hydrogen phosphate.

Psilocin is also known as "4-HO-DMT", "4-hydroxy DMT", "psilocine", "psilocin", or "psilotsin". The 1971 UN Convention does not expressly list species of mushroom (in their natural form) in which the substances mentioned above subsists in the schedule. However, the reach of the 1971 UN Convention is extended to include "preparations", being any solution or mixture, in whatever physical state, containing one or more psychotropic substances, or (ii) one or more psychotropic substances in dosage form. Notwithstanding the forgoing, the UK has controlled both psilocin and (since 2005) fungi containing psilocin.

#### The Misuse of Drugs Act 1971

The Misuse of Drugs Act 1971 ("**MDA**") is the key legislative framework in the United Kingdom as it relates to the possession and various activities associated with any "controlled drugs". The MDA reflects the UK's obligation and commitment to comply with the UN Conventions. The MDA, whilst establishing various criminal offences for the misuse of controlled drugs, enshrines into law the special protection envisaged by the international conventions for controlled drugs to be used for medical and scientific purposes.



The MDA has established three separate classes of controlled drug (Classes A, B and C). Controlled drugs in Class A are subject to the strictest legal controls (which would include cocaine and heroin) given their perceived risk to public health by their misuse.

## The Psychoactive Substances Act 2016

Psychoactive Substances Act 2016 imposes a 'blanket' prohibition on acts of producing, supplying, offering to supply, or importing or exporting, a non-exempted psychoactive substance that is likely to be consumed by individuals for its psychoactive effect. The purpose of this legislation has been to curb the threat to public health and society from the illicit sale of products generally referred to as "legal highs", which are not categorized as a "controlled drugs" under the MDA or medicinal product (as defined by regulation 2 of the Human Medicines Regulations 2012 ("HMR").

## Misuse of Drugs Regulations 2001

In compliance with the UN Narcotics Convention and pursuant to section 7(1) of MDA, the Misuse of Drugs Regulations 2001 ("MDR") regulates the availability of "controlled drugs" that have a recognised and legitimate use by allocating them to one of 5 schedules. Drugs listed under Schedule 1 of MDR can only be possessed or supplied under a Home Office licence and cannot be prescribed by a medical practitioner. The Home Office may grant a special licence for a Schedule 1 controlled drug to be used for research and other purposes. Controlled drugs listed under Schedule 2 and 3 of the MDR can be made available for medical use and are capable of being prescribed by a medical practitioner. Psychedelic drugs (with few exceptions, such as ketamine) are scheduled under Schedule 1 of MDR on the basis that they are perceived as having no benefit to public health. This means that scientific study and research associated with psilocybin isolate would require a Home Office Licence.

#### Human Medicines Regulations 2012

It does not follow that merely because a drug appears in schedule 2 to 5 of the MDR that it may readily be prescribed to human beings. This is because there are strict and complex legal requirements in relation to "medicinal products". Under regulation 46(1), a person "may not sell or supply, or offer to sell or supply, an unauthorised medicinal product". Furthermore, by regulation 46(2), a person may not sell or supply, or offer to sell or supply, a medicinal product otherwise than in accordance with the terms of, (a) a UK marketing authorisation; (b) an EU marketing authorisation; (c) a certificate of registration; (d) a traditional herbal registration; or (d) an Article 126a authorisation. However, regulation 46(1) and (2), do not apply to the sale, supply, or offer for sale or supply, of an "investigational medicinal product" to a person specified in regulation 13(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No.1031) ("CTR"): "for the purposes of administering that product in a clinical trial, provided that the conditions specified in regulation 13(2) of those Regulations are satisfied" (HMR 2012, regulation 46(10)). Regulation 18 of the CTR makes provision for the "authorisation procedure for clinical trials involving general medicinal products". There can be circumstances in which an unauthorised "medicinal product" may be prescribed to fulfil special patient needs but this is subject to very tight and strict restrictions (regulation 167).

#### Scientific research

Some of the drugs listed in Schedule 1 to the MDR are those which scientists would like to research – such as psilocybin. The "public interest" test set out under section 7(4) MDA becomes relevant in this regard. Prohibition is not absolute and permits "research or other special purposes", and that practitioners, pharmacists and persons lawfully conducting retail pharmacy businesses, may be permitted to act in their capacity as such under licence or "other authority issued by the Secretary of State". Thus, a person (or legal entity) may carry out medical and scientific research, even when it relates to a schedule 1 drug - provided that there is official authority to do so (typically by way of a licence). The process for obtaining a licence and securing the authority of the MHRA to carry out clinical trials for example, can be protracted and expensive.

# MHRA – Clinical Trial Authorization

In this paragraph an overview of the MHRA's process for obtaining a Clinical Trial Authorisation ("**CTA**") is set out. Clinical trials of medicines for human use are regulated under the CTR, as referenced above. A CTA together with a positive opinion from an Ethics Committee (as detailed below) must be granted before a clinical trial can proceed.



Two guidance documents were issued in March 2021 by the MHRA to assist with the CTA process, as referenced, which detail the requirements and details of how to submit an application.<sup>3,4</sup> By way of summary, the following documents must be included in the submission package to the MHRA:

- A cover letter;
- A clinical trial application form;
- A protocol document;
- An investigator's brochure or document replacing this;
- An investigational medical product dossier (IMPD) or a simplified IPMD;
- A non-investigational medicinal product dossier if required;
- A summary of scientific advice obtained from the MHRA or any other regulatory authority, if available;
- Manufacturer's authorisation, including the importer's authorisation and Qualified Person declaration on good manufacturing practice for each manufacturing site if the product is manufactured outside the EU;
- A copy of the UK or EMA's decision on the paediatric investigation plan and the opinion of the paediatric committee, if applicable; and
- The content of the labelling of the investigational medicinal product, or justification for its absence.

There are different fees payable dependent on the type of clinical trial application, as listed out in the referenced guidance note.<sup>5</sup>

The initial assessment is completed typically within 30 days of submission, although it can take longer for certain trials for which the MHRA will seek further advice.

The MHRA will confirm the outcome of the assessment of a submission as one of the following, as per Regulation 18(2) of the CTR 2004:

- Acceptance of the request for a clinical trial authorisation;
- Acceptance of the request for a clinical trial authorisation subject to conditions; or
- Grounds for non-acceptance of the request for a clinical trial authorisation.

If the request is not accepted, the applicants will be given the reasoning and must amend the application and resubmit. Additional charges can apply depending on the type of amendments that are to be made.

# Ethics Committee

Approval will also be needed from an ethics committee before the trial begins, as per Regulation 12 of the CTR. This can be done either at the same time or after the submission to the MHRA has been made and are made via the National Research Ethics Service, which is part of the Health Research Authority. Regulation 15 of the CTR lists the considerations that may be taken into account by the ethics committee in making their decision.

# Sponsors

Regulation 3(2) of the CTR provides details of the responsibilities of sponsors of clinical trials. Sponsors need to be established in the UK or a country on an approved country list which initially would include EU/EEA countries. If this is not the case, the sponsor must designate a UK legal representative.

As per Regulation 33 of the CTR, sponsors must submit reports of suspected unexpected serious adverse reactions (both United Kingdom and non-United Kingdom) relevant to a UK trial to the MHRA and the relevant research ethics committee. There is also a requirement to submit annual safety reports under Regulation 35 of the CTR. They must provide investigators with information on safety issues relevant to whether they enrol patients or allow them to continue with the study. The Company has

<sup>&</sup>lt;sup>5</sup> Current MHRA fees - GOV.UK (www.gov.uk)



<sup>&</sup>lt;sup>3</sup> Clinical trials for medicines: apply for authorisation in the UK - GOV.UK (www.gov.uk)

<sup>&</sup>lt;sup>4</sup> Clinical trials for medicines: manage your authorisation, report safety issues - GOV.UK (www.gov.uk)

secured approval however the UK trial has been paused while the Company prioritises the Palliative Care Clinical Trial in Australia.

The CTR require sponsors to provide adequate insurance or indemnity to cover liabilities that may arise in relation to the clinical trial. The MHRA expects that a sponsor's insurance policy or indemnity will reflect the form recommended by the Association of the British Pharmaceutical Industry (ABPI) Clinical Trial Compensation Guidelines.

## Recreational Use of Psychedelics

In the United Kingdom, the law does not permit for a market to be established for the "recreational" sale or use of psychedelic products, as is consistent with the approach adopted uniformly amongst developed nations. The Company is therefore strictly prohibited from engaging in any activities associated with the recreational sale or use of psychedelic drugs in the United Kingdom, and its activities are strictly confined to medical and scientific research having obtained all necessary licences, authorisations and approvals.

There is nothing under existing UK law that would legally permit the operation (in the UK) of retreats administering psilocybin in any form or to undertake the commercial sale or production of psilocin or fungi containing psilocin for "recreational" purposes.

## Australia

The Therapeutic Goods Administration in Australia (**"TGA"**) is Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods, and the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation. Such legislation includes The Therapeutic Goods Act 1989 (**"TG Act"**), Regulations and Orders which set out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (ARTG).

## Registration of medicines

For a prescription medicine to be registered in the ARTG, a sponsor of the product (usually a pharmaceutical company such as Psyence) is required to submit a dossier of evidence on the clinical efficacy, safety and manufacturing quality for evaluation by the TGA. Clinical trials of medicines and biologicals regulated under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes are subject to the TGA's Good Clinical Practice (GCP) Inspection Program. The TGA has issued a handbook which provides guidance on the legislative, regulatory and good clinical practice (GCP) requirements when conducting clinical trials in Australia using 'unapproved' therapeutic goods in order to assist trial sponsors, Human Research Ethics Committees (HRECs), investigators and approving authorities (institutions) in understanding their roles and responsibilities under the therapeutic goods legislation.

### Scheduling of Psilocybin

Until recently, psilocybin was included in Schedule 9 (Prohibited Substances) of the Poisons Standard which, because of interaction with state and territory regulation, largely restricted the lawful supply of goods containing psilocybin to clinical trial settings only. However, effective 1 July 2023, the TGA made the decision to down schedule psilocybin to Schedule 8 in the Poisons Standard when used in respect of certain conditions, namely for the treatment of treatment-resistant depression.

#### Importation

To import products that contain a controlled substance (such as psilocybin), the importer requires both an exemption, approval or authority under the TG Act and a licence and/or permit to import from the Office of Drug Control under the Customs (Prohibited Imports) Regulations 1956. Licences and permits to import psilocybin are only granted by the Office of Drug Control where the use of the substance is permitted by the relevant state or territory under their respective medicines and poisons legislation and the use of the of psilocybin is to be prescribed by an Authorised Prescriber or for an authorised clinical trial.

Psyence will monitor the evolution of Australia's regulations as they pertain to psilocybin and the conduct of clinical trials in Australia.



# Corporate Governance and Compliance Program

Corporate governance refers to the policies and structure of the board of directors of a company, whose members are elected by and are accountable to the shareholders of the company. Corporate governance encourages the adoption of policies to ensure the board of directors recognizes the principles of good management. The Board is committed to sound corporate governance practices; as such practices are both in the interests of shareholders and contribute to effective and efficient decision-making. The Company has adopted corporate governance policies and guidelines (the **"Guidelines"**) governing key matters and has accordingly enacted: (a) internal guidelines to control transactions involving its securities by all Company directors, officers and insiders (among others) to ensure that such parties are aware of and comply with their legal obligations with respect to "insider trading" and "tipping"; and (b) timely disclosure and confidentiality guidelines to ensure the timely and accurate disclosure of material information relating to the Company and/or its material subsidiaries in accordance with applicable securities laws and stock exchange rules, to prevent the improper use or disclosure of material information about the Company and to promote an understanding of and compliance with legal requirements and stock exchange rules.

The Board shall: (a) review the Guidelines on an annual basis; and, (b) at a more appropriate time in the future, (i) implement additional corporate governance policies and guidelines; (ii) implement measures and processes to review critically each director's continuation on the Board every year considering, among other things, a director's service on other boards and the time involved in such other service; and (iii) establish a process for the evaluation of the performance of the Board and each of its committees.

The Company engages professional advisors (legal, financial, and technical) with the relevant expertise to provide assistance in navigating and managing the political, legal and cultural realities of the jurisdictions in which it operates and the impact it may have on the Company's business or operations on an as-needed basis. Additionally, the Company's management team has a long and successful history of doing business in Canada, United Kingdom and Southern Africa. With respect to Southern Africa specifically, the Company's management team has experience engaging with local communities and tribal chiefs as well as a working knowledge of the region's local legal, regulatory and political landscape. The management team's technical division is well acquainted with the region's natural terrain as well as its climactic and infrastructure related challenges.

The Company, via its subsidiaries has a local presence in each of the jurisdictions in which the Company operates, which allows the Company to manage government and regulatory authorities as well as address any request from such authorities. For example, the Company has appointed a Country Manager and a Government Liaison Officer who travel to Lesotho from neighbouring South Africa regularly.

The Company managers and monitors compliance with applicable laws in each jurisdiction in which it operates through its general legal counsel and Chief Financial Officer, who engage, as needed, local counsel in every jurisdiction, who provide legal opinions or advice in each of these jurisdictions regarding: (a) compliance with applicable laws and regulatory frameworks, (b) applications, maintenance and renewals of licences and permits, and (c) changes in the legal landscape affecting the Company operations.

The Company has received independent local legal opinions confirming the lawfulness of the Company's activities in Canada, the UK and Lesotho and has engaged local legal counsel in South Africa to ensure compliance with material legal, regulatory and governmental developments as they pertain to and affect the Company's operations. The Company's operations are conducted in compliance with local laws where such activities are permissible and either (a) do not require any specific legal or regulatory approvals, or (b) the Company has obtained all necessary legal and/or regulatory approvals.

The Company works with third party facilities, research institutions, and contract manufacturers who require regulatory licensing to handle scheduled drugs. Before commencing any commercial or other ventures with such third parties, the Company conducts a high-level legal, regulatory and quality control



due diligence to verify claims made by such third parties. The Company ensures that contracted third parties provide the necessary warranties and undertakings required to ensure compliance with applicable laws in contracts concluded with such parties. Failure of third parties to comply with applicable laws constitutes a material breach of contract, giving rise to a contractual right on the part of the Company to terminate any contract with such offending third party.

The Company held its annual general meeting of shareholders on March 9, 2023 (the "2023 AGM").



# **Overall Performance**

# **Financial Information**

The Company's most recent financial year end was March 31, 2023. This MD&A presents information relating to the period April 1, 2023 to September 30, 2023 with comparative information being shown for the period April 1, 2022 to September 30, 2022 ("**comparative period**").

# Results and Overview of operations for the second fiscal quarter to September 30, 2023

### Revenue and results

The Company did not report revenue from operations for the 3-month period ended September 30, 2023 (comparative period: \$0). The total comprehensive loss for the 3-month period ended September 30, 2023, was \$544,052 (comparative period: \$1,051,924).

The Company did not report revenue from operations for the 6-month period ended September 30, 2023 (comparative period: \$0). The total comprehensive loss for the 6-month period ended September 30, 2023, was \$2,825,699 (comparative period: \$2,283,762).

The total comprehensive loss relates to the overall growth of the Company as it continues to develop the drug development business and perform clinical trials.

## Sales and marketing costs

For the 3-month period ended September 30, 2023, the Company's sales and marketing costs of \$6,915 were incurred for fundraising activities, conferences, content, promotional materials and website design costs (comparative period: \$122,797).

For the 6-month period ended September 30, 2023, the Company's sales and marketing costs of \$8,867 were incurred for fundraising activities, conferences, content, promotional materials and website design costs (comparative period: \$219,303).

The Company incurs sales and marketing expenses for raising awareness and funds for the Company and its clinical trials. This decrease in costs is because the Company has shifted its focus towards the execution of its clinical trials and cost savings measures implemented.

# Research and development

For the 3-month period ended September 30, 2023, the Company incurred research and development costs of \$43,644 (comparative period: \$41,846).

This consists of \$55,098 (comparative period: \$39,312) spent for the purposes of growing natural psilocybin mushrooms in compliance with the Mind Health Lesotho Permit and (\$11,454) (comparative period: \$2,534) on the Palliative Care Clinical Trial, \$0 (comparative period: \$0) on drug licencing fees and \$0 (comparative period: \$0) on drug development.

For the 6-month period ended September 30, 2023, the Company incurred research and development costs of \$1,172,227 (comparative period: \$291,258).

This consists of \$110,015 (comparative period: \$83,812) spent for the purposes of growing natural psilocybin mushrooms in compliance with the Mind Health Lesotho Permit and \$1,060,099 (comparative period: \$107,446) on the Palliative Care Clinical Trial, \$0 (comparative period: \$100,000) on drug licencing fees and \$2,113 (comparative period: \$0) on drug development.

The increase in costs for the period were as result of increased production in line with the production facility expansion, clinical trial activity which has increased as Psyence commenced in its trial program



and drug development for clinical trials. Costs incurred for the growing of mushrooms include grow consumables, laboratory testing, analysis of the mushrooms, and other direct growing costs.

## General and administration costs

For the 3-month period ended September 30, 2023, the Company incurred a reversal general and administrative costs of \$809 which consisted of bank fees, filing fees, general office expenditure, facility maintenance, salaries and wages and operational costs (comparative period, \$226,417).

For the 6-month period ended September 30, 2023, the Company incurred general and administrative costs of \$240,646 which consisted of bank fees, filing fees, general office expenditure, facility maintenance, salaries and wages and operational costs (comparative period, \$425,107).

General and administrative costs decreased in comparison to the comparative period as a result of a reversal of previously expensed share based compensation by the Company. All other costs have remained consistent.

## Professional and consulting fees

For the 3-month period ended September 30, 2023, professional and consulting fees totalling \$365,785 were incurred (comparative period: \$563,166). This consisted of \$244,438 (comparative period: \$413,603) paid to consultants for product development, financial, business strategies and administrative services, \$0 (comparative period: \$3,833) in relation to management fees, legal fees of \$59,411 (comparative period: \$96,936) paid to legal practitioners for various corporate matters, whilst \$664 (comparative period: \$30,409) was paid for accounting services and \$61,272 (comparative period: \$18,384) for audit fees.

The professional and consulting fees for the quarter decreased from the preceding quarter due to a reversal of previously expensed options. All other costs have decreased due to cost saving measures implemented by the Company.

For the 6-month period ended September 30, 2023, professional and consulting fees totalling \$1,204,566 were incurred (comparative period: \$1,146,409). This consisted of \$686,176 (comparative period: \$838,814) paid to consultants for product development, financial, business strategies and administrative services, \$0 (comparative period: \$8,388) in relation to management fees, legal fees of \$433,066 (comparative period: \$216,311) paid to legal practitioners for various corporate matters, whilst \$1,225 (comparative period: \$35,066) was paid for accounting services and \$84,100 (comparative period: \$47,830) for audit fees.

The professional and consulting fees for the period increased from the comparative period due to legal fees increasing predominantly in connection with the proposed Newcourt transaction. This increase in legal fees was offset by the reversal of previously expensed options, leading to a small overall increase in professional and consulting fees for the period.

#### Other costs

The depreciation and amortization charge for the current period was \$46,451 in total (comparative period: \$39,418). Of this amount, \$1,311 was charged for right-of-use assets (comparative period: \$1,443) and \$43,880 (comparative period: \$36,711) was depreciation on computer equipment, buildings, production equipment, furniture and leasehold improvements. The amortization of intangible assets was \$1,260 for the period (comparative period: \$1,264). This increase in depreciation is due to the upgrades of the Psyence Production Facility.

MindHealth Lesotho has a sub-lease agreement, for a portion of land situated at a cultivation site in Kolojane in the Berea District of Lesotho. The Company has developed a laboratory, production and processing facility on this portion of land (the Psyence Production Facility) at a cost of \$757,254 and



this has a carrying value of \$582,537. In addition to the leased portion of land, MindHealth Lesotho is entitled to use the essential infrastructure and related services available at the cultivation site. The monthly rental, sewerage and drainage is Lesotho Loti 3,485 per month. The initial term of the lease is nine years commencing 1 June, 2020 and ending May 21, 2029. Thereafter, the Company has the option to renew the lease for a further ten-year period for a maximum of five times total. The lease is reflected on the consolidated statement of financial position as a right-of-use asset and a lease liability of \$40,848 and \$43,278, respectively.

# Total assets at quarter end September 30, 2023

Total assets for the period were \$2,180,184 and comprised predominantly of cash and cash equivalents of \$856,496, property, plant and equipment ("PPE") of \$625,810 and prepaids of \$604,747.

The Company has bank accounts denominated in Canadian dollars, US dollars, Great British pounds, Australian dollars, South African rands and Lesotho loti. At quarter end the Company had the following currency exposures on these accounts:

-	Canadian bank accounts	: \$217,794
		\$191,999 (US\$141,406 – denominated in US dollars)
-	Lesotho bank accounts:	\$135 (US\$100 – denominated in US dollars)
		\$5,527 (LSL77,176 – denominated in Lesotho loti)
-	South African accounts:	\$4,611 (ZAR64,375 – denominated in South African rand)
		\$21,678 (US\$16,000 – denominated in US dollars)
-	Australian accounts:	\$407,087 (AUD\$466,683 – denominated in Australian dollars)
		\$7,665 (US\$5,653 – denominated in US dollars)



# **Operations**

# **Quarterly Results of Operations**

	Quarter end September 30, 2023 \$	Quarter end June 30, 2023 \$	Quarter end March 31, 2023 \$	Quarter end December 31, 2022 \$
Total Revenue	-	-	-	-
Total Comprehensive Loss	544,053	2,281,650	3,150,102	743,364
Loss per-share – Basic and diluted	(0.00)	(0.02)	(0.03)	(0.01)
Weighted Average Number of Shares	132,407,414	127,030,394	97,876,442	87,249,422

	Quarter end September 30, 2022 \$	Quarter end June 30, 2022 \$	Quarter end March 31, 2022 \$	Quarter end December 31, 2021 \$
Total Revenue	-	-	-	-
Total Comprehensive Loss	1,051,925	1,231,837	1,019,149	1,255,854
Loss per-share – Basic and diluted	(0.01)	(0.01)	(0.01)	(0.01)
Weighted Average Number of Shares	85,528,931	85,528,931	85,528,931	85,528,931

The consolidated financial statements have been prepared in accordance with IFRS as issued by the International Accounting Standards Board (IASB), and the interpretations of the IFRS Interpretations Committee (IFRIC), effective for the Company's reporting for the quarter ended September 30, 2023.

Mind Health Lesotho, Psyence South Africa and Psyence Australia are subsidiaries of the Company which have functional currencies of Lesotho loti, South African rand and US Dollars respectively that differs to the Company's presentation currency (Canadian dollars).



# Liquidity and Capital Resources

	Three months end	ded September 30,	Six months ended September 30,		
CAD \$	2023	2022	2023	2022	
Cash used in operating activities	(982,602)	(922,791)	(3,592,516)	(1,800,695)	
Cash used in investing activities Cash	(79,270)	(93,368)	(80,187)	(388,336)	
raised from financing activities	1,232,198	(796)	2,145,847	(1,620)	
Total Cash Movement	170,326	(1,016,955)	(1,526,856)	(2,190,651)	

	3 months ended September 30, 2023	6 months ended September 30, 2023			
	This primarily relates to cash used for operating expenses including research and development expenses, salaries, professional fees, and other general and administration expenses. Cash flows from operating activities exclude expenses not affecting cash, such as share based compensation expenses, depreciation, unrealized foreign exchange gains or losses, and net changes in non-cash balances relating to operations.				
Net cash used in operating activities	For the 3-month period ended September 30, 2023, cash used in operating activities was \$982,602 driven by a net loss of \$488,844 and non-cash unrealized foreign exchange gain of \$7,792 partially offset by the following non-cash items: reversal of share-based compensation of \$215,010, share of loss from joint venture of \$1,959, impairment of joint venture of \$880, accretion consideration of \$274, interest expense of \$37,615 and depreciation and amortization of \$23,373.	For the 6-month period ended September 30, 2023, cash used in operating activities was \$3,592,516 driven by a net loss of \$2,724,184 and non-cash unrealized foreign exchange gain of \$6,256 partially offset by the following non-cash items: reversal of share-based compensation of \$11,010, share of loss from joint venture of \$54,131, impairment of joint venture of \$51,292, accretion consideration of \$551, interest expense of \$37,615 and depreciation and amortization of \$46,451.			
Net cash used in investing activities	<ul> <li>For the 3-month period ended September 30, 202, cash flows were mainly driven by:</li> <li>Additions to property and equipment \$82,109 and repayment from Good Psyence of \$2,839.</li> </ul>	<ul> <li>For the 6-month period ended September 30, 2023, cash flows were mainly driven by:</li> <li>Additions to property and equipment \$83,026 and repayment from Good Psyence of \$2,839.</li> </ul>			
Net cash from (used in) financing activities	<ul> <li>For the 3-month period ended September 30, 2023, cash flows were mainly driven by:</li> <li>Repayment of lease liabilities of \$754</li> <li>Proceeds from private placements of \$278,472 and</li> <li>Proceeds from loan of \$954,480.</li> </ul>	<ul> <li>For the 6-month period ended September 30, 2023, cash flows were mainly driven by:</li> <li>Repayment of lease liabilities of \$1,506</li> <li>Proceeds from private placements of \$1,192,873 and</li> <li>Proceeds from loan of \$954,480.</li> </ul>			



# Liquidity

Since incorporation, the operations have been solely financed from the issuance of equity. The Company's main use for liquidity is to fund scientific research, clinical studies, product development and manufacturing, salaries and professional and consulting fees. Construction of phase 2 of the Psyence Production Facility is only planned to commence when market demands dictating the supply of product require it. The ability to fund operations and to make planned cash flows are subject to prevailing economic conditions, regulatory and financial, business, and other factors, some of which are beyond the Company's control.

As at September 30, 2023 the Company had cash balances of \$856,496 and negative working capital of \$1,417,868. Working capital represents the excess of current assets over current liabilities. The Company is in its clinical trial and drug development stage as it researches and develops its IP portfolio in anticipation of manufacturing in the future. Therefore, the Company will not be able to generate sufficient amounts of cash and cash equivalents from its revenue generating operations in the short term. Accounts payable and accrued liabilities have contractual maturity dates within one year, lease liabilities which have contractual maturity dates spanning 7 years and amounts due to related parties have a contractual maturity date within one year. All significant contractual obligations and commitments are disclosed under Discussion of operations above and there are no other significant obligations maturing in the short term. The Company does not believe that it will be able to fund operations and significant projects within the next 12 months from the available cash and cash equivalents without raising additional financing. The Company expects to remedy this working capital deficiency through the further issuances of common shares through private placements over the next 12 months. The Company prioritises expenditure, both capital and operational, by regularly reviewing its available cash and cash equivalent balances against the spend required to deliver on its key strategic objectives and milestones.

The Company's current expenditure obligations include commitments for those projects described in "*Business overview*" above. The Company expects to continue funding these projects with available cash and cash equivalents, and therefore, is subject to risks including, but not limited to, an inability to raise additional funds through the issuance of equity, debt instruments or similar means of financing to support the Company's continued development, including capital expenditure requirements, operating requirements and to meet its liabilities and commitments at they become due.

The Company has experienced operating losses and cash outflows from operations since incorporation and by nature of its business, will require ongoing financing to continue its research and development. It will require ongoing financing in order to continue production, research and development activities. The Company's ability to access both public and private capital is dependant upon, among other things, general and sectoral market conditions and the capital markets generally, market perceptions about the Company and its business operations, and the trading prices of the Company's securities from time to time. There can be no assurance that additional funds can be raised upon terms acceptable to the Company, or at all, as funding for early-stage companies remain challenging generally.

The Company's primary capital needs are funds to advance its research and development activities and for working capital purposes. These activities include staffing, pre-clinical studies, clinical trials and administrative costs. There are uncertainties regarding its ability to continue as a going concern. The Company has not earned any significant. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favourable for the Company as those previously obtained, or at all. See "*Risk Factors*" below.

Lesotho is part of the Common Monetary Area ("CMA"), together with Namibia, South Africa and eSwatini (formerly Swaziland). There are no foreign exchange restrictions between banks of the CMA member countries in respect of cross-border transactions amongst themselves. Please refer to "*Exchange Controls, Currency Fluctuations and Credit Risks – Lesotho and South Africa*" below for more information on the exchange control regulations applicable in these CMA countries in respect of non-CMA countries. These exchange control processes are largely administrative in nature but may cause delays in the transfer of monies into and out of Lesotho and/or South Africa.



The Company manages its liquidity risk in these Southern African jurisdictions by ensuring that the inward flows of funds occur by way of a loan which is approved upfront by the necessary exchange control authorities. Once the inward loan is approved, the repayment of such loans is approved and the risk that funds will not be permitted to be repatriated is extinguished. Any liquidity risk in these Southern African jurisdictions is further mitigated by the fact that the Company does not hold excessive funds in these jurisdictions and manages its cash flows to meet the Company's Southern African commitments only.

# **Off Balance Sheet Arrangements**

The Company has not had any off-balance sheet arrangements from the date of its incorporation to the date of this MD&A.

# Transactions between Related Parties

# Compensation to key management personnel

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly. Key management personnel, as defined by International Accounting Standards 24 *Related Party Disclosures*, include the Company's executive officers and Board of Directors. For the reporting period, they are as follows: Jody Aufrichtig, Dr. Neil Maresky, Warwick Corden-Lloyd, Corden-Lloyd Consulting, Dr. Amza Ali, Alan Friedman, Bayline Capital Partners Inc., Gavin Basserabie, Marvin Singer and Christopher Bull. Dr Amza Ali resigned from his position on the board effective September 1, 2022 and Gavin Basserabie resigned from his position on the board effective November 28, 2022. Christopher Bull was appointed on July 11, 2023 to the board of directors.

Short term benefits consist of consulting fees, payroll and other benefits paid to key management personnel.

Key Management Personnel	Three months Ending September 30, 2023	Three months Ending September 30, 2022	Six months Ending September 30, 2023	Six months Ending September 30, 2022
Short term benefits	180,226	258,575	364,370	483,260
Share-based compensation	(5,449)	52,815	150,172	133,688
Total	174,777	311,390	514,542	616,948

# Balances

As at September 30, 2023, the Company held amounts totaling \$28,111 (September 30, 2022 - \$106,752) in accounts payable and accrued liabilities. These are amounts owing to key management personnel.



# Subsequent Highlights

The loan agreement with RH Capital Finance Co., LLC was repaid in full on October 5, 2023 when the Company received the research and development rebate of AUS \$1,291,482 (\$1,127,076) from the Australian Taxation office which was utilised to settle the loan payable.

On October 30, 2023,the Company issued 35,810 shares for \$4,297 in relation to private placements. On this same date, the shares to be issued on the balance sheet amounting to 1,320,000 shares were issued (refer to note 11) as well as 2,297,051 common shares which were issued at a price of CAD\$0.12 per common share for a portion of the purchase price of equipment supplied to the Company in relation to the previously announced partnership with Eden Labs.

### **Financial Instruments and Other Instruments**

The Company's financial instruments consist of cash, other receivables, prepaids, accounts payable and accrued liabilities and amounts due to related parties. These financial instruments arise in the normal course of business and are classified and measured at amortized cost.

Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest, currency or credit risks arising from these financial instruments. The Company does not partake in hedging activities.

The fair values of these financial instruments approximate their carrying values. As required by IFRS 9 *Financial Instruments*, the Company applies a forward-looking expected credit loss (ECL) model, at each balance sheet date, to financial assets measured at amortized cost to determine whether the asset is impaired. As at September 30, 2023, loss on impairment of loan to JV recognized for \$51,292.

In the normal course of business, the Company is exposed to a variety of financial risks: credit risk, liquidity risk, foreign exchange risk and interest rate risk. These financial risks are subject to normal credit standards, financial controls, risk management as well as monitoring. The Company's Board of Directors has overall responsibility for the establishment and oversight of the Company's risk management framework.

#### **Credit risk**

Credit risk arises from cash and cash equivalents, restricted cash, other receivables and loan to joint venture. The maximum exposure to credit risk is equal to the carrying value of the financial assets. The objective of managing counterparty credit risk is to prevent losses on financial assets. The Company minimizes the credit risk of cash by depositing with only reputable financial institutions. The Company also assesses the credit quality of counterparties, taking into account their financial position, past experience and other factors.

Cash consists of bank balances and an amount held in trust by a brokerage firm as security for foreign currency exchanges. Other receivables mainly consist of federal sales tax credits.

#### Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due.

As at September 30, 2023, the Company's financial liabilities consist of account payable, accrued liabilities, and lease liabilities.

The Company manages liquidity risk through an ongoing review of future commitments and cash balances available. Historically, the Company's main source of funding has been the issuance of common shares for cash, primarily through private placements. The Company's access to financing is always uncertain. There can be no assurance of continued access to significant equity or debt funding.



Financial Instrument Maturity (\$)	Less than 1 year	2-3 years	4-5 years	After 5 years	Total
Accounts payable and accrued liabilities	1,381,893	-	-	-	1,381,893
Lease liability	3,009	6,149	6,340	37,908	53,135
Total	1,384,902	6,149	6,340	37,908	1,920,532

The following table illustrates the contractual maturities of financial liabilities as at September 30, 2023:

# Foreign exchange risk

Foreign currency risk is the risk that the fair values of future cash flows of a financial instrument will fluctuate because they are denominated in currencies that differ from the respective functional currency.

The Company operates internationally and is exposed to foreign exchange risk from the LSL, ZAR, AUD and USD. Foreign exchange risk arises from transactions as well as recognized financial assets and liabilities denominated in foreign currencies.

A 10% adverse change in exchange rate would have resulted in a loss of \$45,320 as at September 30, 2023 (September 30, 2022 - \$24,978).

Management mitigates the risk of adverse exchange rate movements by holding funds in Lesotho, South Africa and Australia in US dollars. The money held in these countries are only converted into local currency once it is required to be spent. The Company mitigates the currency risk by keeping excess funds in US Dollars and exchange control risk by keeping excess funds in Canada.

# Interest rate risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company has no significant interest-bearing assets or liabilities and therefore its income and operating cash flows are substantially independent of changes in market interest rates. Management therefore regards liquidity risk to be low.

# **Capital management**

The Company's objectives when managing its capital are to safeguard its ability to continue as a going concern, to meet its capital expenditures for its continued operations, and to maintain a flexible capital structure which optimizes the cost of capital within a framework of acceptable risk. The Company manages its capital structure and adjusts it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust its capital structure, the Company may issue new common shares, issue debt, or acquire or dispose of assets. The Company is not subject to externally imposed capital requirements.

Management reviews its capital management approach on an ongoing basis. The Company considers its shareholders' equity balance as capital.



# **Risk Factors**

#### An investment in the Company is subject to various risks and should be considered highly speculative.

Prior to making an investment decision, investors should consider the investment risks set forth below which are in addition to the usual risks associated with an investment in a business at an early stage of development. The directors of the Company consider the risks set forth below to be the most significant, but do not consider them to be all of the risks associated with an investment in securities of the Company. If any of these risks materialize into actual events or circumstances or other possible additional risks and uncertainties of which the directors are currently unaware or which they consider not to be material in connection with the Company's business, actually occur, the Company's assets, liabilities, financial condition, results of operations (including future results of operations), business and business prospects, are likely to be materially and adversely affected. In such circumstances, the price of the Company's securities could decline, and investors may lose all or part of their investment.

#### Initial lack of business diversification

Because the Company will be initially focused on research and development, cultivation and production of psilocybin mushrooms and functional over-the-counter mushroom products, the prospects for the Company's success will be dependent upon the future performance and market acceptance of the Company's intended facilities, products, processes and services. Unlike certain entities that have the resources to develop and explore numerous product lines or operate in multiple industries, the Company does not anticipate having the ability to immediately diversify or benefit from the possible spreading of risks or offsetting of losses. The Company operates in both the psychedelic and non-psychedelic areas of the mushroom industry. Again, the prospects for the Company's success may become dependent upon the development or market acceptance of a very limited number of facilities, products, processes or services.

#### Regulatory Compliance Risks

The Company operates in the Kingdom of Lesotho pursuant to licenses and authorizations granted by Lesotho governmental authorities. To a lesser extent, the Company also has nascent operations focused on product development in South Africa. Certain activities conducted by the Company are permissible under the enabling Lesotho regulatory regimes, which are less restrictive and onerous than the Canadian regulatory regime.

In the past, Canadian courts and regulatory authorities have taken the view that it is not contrary to Canadian federal or provincial law for a person to be engaged in, or for an entity to hold interests in affiliates that are engaged in certain regulated activities where such activities may be regulated differently than in the home jurisdictions and have enforced extra-territorial laws even where such laws (or regulatory regimes applicable to certain activities or industries) differ from those in the Canadian jurisdiction. There still remains a risk that Canadian courts or applicable Canadian or other governmental authorities may take a contrary view with respect to the business of the Company and view the Company as having violated their local laws, despite the Company having obtained all applicable Lesotho licenses or authorizations (and to a lesser extent, applicable South Africa licenses or authorizations (where required)). Therefore, there is a risk that civil and criminal proceedings, including class actions, could be initiated against the Company. Such potential proceedings could involve substantial litigation expense, penalties, fines, seizure of assets, injunctions or other restrictions being imposed upon the Company or its business partners, while diverting the attention of key executives. Such proceedings could have a material adverse effect on the Company's business, revenues, operating results and financial condition as well as an impact upon the Company's reputation.

#### There is no assurance that the Company will become profitable or pay dividends

There is no assurance as to whether the Company will become profitable or pay dividends. The Company has incurred and anticipates that it will continue to incur substantial expenses relating to the development and initial operations of its business. The payment and amount of any future dividends



will depend upon, among other things, the Company's results of operations, cash flow, financial condition and operating and capital requirements. There is no assurance that future dividends will be paid, and, if dividends are paid, there is no assurance with respect to the amount of any such dividends.

# Material uncertainty about the Company's ability to continue as a going concern

The Company's ability to continue as a going concern is dependent upon its ability to raise funding, generate revenue and achieve profitable operations and, in the meantime, to obtain the necessary financing to meet its obligations and repay its liabilities when they become due. External financing, predominantly by the issuance of equity and debt, will be sought to finance the operations of the Company; however, there can be no certainty that such funds will be available at terms acceptable to the Company, or at all.

# Substantial additional funding for the Palliative Care Clinical Trial PubCo

Conducting clinical trials and developing biopharmaceutical products is expensive and time consuming, and we expect to require substantial additional capital to conduct research, preclinical studies and clinical trials for the current and future trials, seek regulatory approvals for our drug candidates and launch and commercialize any products for which Psyence may receive regulatory approval, including building our own commercial sales, marketing and distribution organization. Our management and strategic decision makers have not made decisions regarding the future allocation of certain resources among Psyence's pipeline of trials, but continue to evaluate the needs and opportunities with respect to each of these trials routinely and on a case-by-case basis. Because the outcome of any preclinical or clinical development and regulatory approval process is highly uncertain, Psyence cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and potential commercialization of its drug candidates and any future drug candidates it may identify.

#### Additional unforeseen costs due to health and medical regulators

Due to the numerous risks and uncertainties associated with the development of its drug candidates, Psyence is unable to predict the timing or amount of its expenses, or when it will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, its expenses could increase beyond current expectations if Psyence is required by the TGA, FDA, the EMA, MHRA, or other comparable foreign regulatory authorities to perform preclinical studies or clinical trials in addition to those that Psyence currently anticipates, or if there are any delays in any of Psyence's or its future collaborators' clinical trials or the development of the existing drug candidates and any other drug candidates that Psyence may identify. Even if Psyence's existing drug candidates or any future drug candidates that Psyence may identify are approved for commercial sale, Psyence anticipates incurring significant costs associated with commercializing any approved product and ongoing compliance efforts.

#### Commercialization and Marketing of Products

The Company is reliant on employees and third-party consultants and service providers to assist in investigating the process of developing and commercializing its psilocybin mushroom products. No assurance can be given that the results of these investigations will determine that manufacturing and distribution of its products will be feasible or commercially viable. A failure to obtain satisfactory results on these investigations could have a material adverse effect on the Company's business and may adversely affect the Company's ability to begin earning revenue.

#### Risk of failure for drug candidates proceeding through clinical trials

Psyence has no registered pharmaceutical products on the market, and its new potential psilocybinbased drug candidates are currently either in the preclinical or clinical development phase. Psyence's



ability to achieve and sustain profitability with respect to its drug candidates in which psilocybin is featured as the active pharmaceutical ingredient depends on obtaining regulatory approvals for and, if approved, successfully commercializing, its drug candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of its current or future drug candidates, Psyence or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity and potency of its drug candidates.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. Psyence may suffer significant setbacks in its clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials.

# Supply chain interruptions during the development of our drug candidates

There are few licensed suppliers of input materials for the manufacture of Psyence's drug candidates. Any loss of stored materials or facilities through fire, theft, or other causes could have an adverse effect on Psyence's ability to procure the drug candidate materials and continue product development activities. Furthermore, Psyence is largely dependent on Filament for the supply of PEX010, and despite Psyence's rights to manufacture the drug candidate itself or through a third-party contract manufacturer (**"CMO"**) in the event that Filament is unable to meet an order or demand for product, any interruption in Filament's supply chain will lead to delays in Psyence's drug development timelines. Furthermore, Filament will be required to continue to meet regulatory requirements applicable to the PEX010 drug candidate and maintain GMP compliant standards which dictate the minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. There can be no assurances that Filament or any CMOs will be able to meet Psyence's timetable and requirements or carry out their contractual obligations in accordance with the applicable regulations.

In general, Psyence's dependence upon third parties for the supply of Psyence's drug product may adversely affect profit margins and Psyence's ability to develop and deliver viable end products on a timely and competitive basis.

# Reliance on third parties to conduct our clinical trials

Psyence relies on iNGENū to conduct clinical development activities with Psyence's drug candidates, which activities involve trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. Additionally, we expect to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract development and manufacturing organizations ("CDMOs") and strategic partners to conduct our preclinical studies under agreements with us and in connection with our clinical trials. We expect to have to negotiate budgets and contracts with CROs, trial sites and CDMOs, which may result in delays to our development timelines and increase costs. We will rely heavily on these third parties over the course of our clinical trials and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff, and we cannot control whether or not they devote sufficient time and resources to our drug candidates. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.



# Reliance on Third Party IP

We do not currently own any granted patents, and we are heavily reliant upon a number of license agreements under which we are granted rights to intellectual property that are important to our business, and we may need or choose to enter into additional license agreements in the future. Specifically, our business and active Phase IIb clinical trial (the Palliative Care Clinical Trial) are highly dependent on the Filament Licensing Agreement, which expires in April 2027. Until we develop own drug candidates, the termination, non-renewal or hinderance of use of the license granted under the Filament Licensing Agreement would have a material adverse effect on our ability to develop our drug candidates as we currently do. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates.

# Additional Risks related to doing Business Internationally

International markets will be a focus for expansion and revenue growth for the Company. Several factors, including legal and regulatory compliance and weakened economic conditions in any of the international jurisdictions in which the Company expects to do business or have projects, could adversely affect such expansion and growth. Additionally, the Company's entry into new international jurisdictions requires management attention and financial resources that would otherwise be spent on other parts of the business. Some of the countries in which the Company expects to sell products are to some degree subject to political, economic, and/or social instability. International business operations expose the Company to risks and expenses inherent in operating or selling products in foreign jurisdictions, and developing and emerging markets in particular, where these risks may be heightened. In addition to the risks mentioned elsewhere, these risks and expenses could have a material adverse effect on the Company's business, results of operations or financial condition and include without limitation:

- adverse currency rate fluctuations;
- risks associated with complying with laws and regulations in the countries in which the Company expects to sell products, and requirements to apply for and obtain licenses, permits or other approvals and the delays associated with obtaining such licenses, permits or other approvals;
- multiple, changing and often inconsistent enforcement of laws, rules and regulations;
- risks associated with reliance on international agents and representatives, including the possible failure of such agents and representatives to appropriately understand, represent and effectively market the Company's products;
- the imposition of additional foreign governmental controls or regulations, new or enhanced trade restrictions or non-tariff barriers to trade, or restrictions on the activities of foreign agents, representatives and distributors;
- increases in taxes, tariffs, customs and duties, or costs associated with compliance with import and export licensing and other compliance requirements;
- the imposition of restrictions on trade, currency conversion or the transfer of funds or limitations;
- the imposition of Canadian and/or other international sanctions against a country, company, person or entity with whom the Company does business that would restrict or prohibit the Company's ability to carry out its operations in Lesotho;
- downward pricing pressure on the Company's products in the international markets, due to competitive factors or otherwise;
- laws and business practices favouring local companies;



- political, social or economic unrest or instability, including without limitation military conflicts and acts of terrorism, military repression, war or civil war, social and labour unrest, organized crime, hostage-taking and violent crime;
- expropriation and nationalization and/or renegotiation or nullification of necessary licenses, approvals, permits and contracts;
- greater risk on credit terms, longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- difficulties in enforcing or defending intellectual property rights; and
- the effect of disruptions caused by severe weather, natural disasters, outbreak of disease or other events that make travel to a particular region less attractive or more difficult.

Governments in certain foreign jurisdictions intervene in their economies, sometimes frequently, and occasionally make significant changes in policies and regulations. Operations may be affected in varying degrees by government regulations with respect to, but not limited to, restrictions on doing business, price controls, export controls, currency remittance, importation of product and supplies, income and other taxes, royalties, the repatriation of profits, expropriation of property, foreign investment, maintenance of concessions, licenses, approvals and permits, environmental matters, land use, land claims of local people, water use and workplace safety. Furthermore, some of the Company's operations are conducted in parts of the world that experience illegal sales practices or corruption or are operated under legal systems susceptible to undue influences to some degree. Although the Company has policies and procedures in place that are designed to promote legal and regulatory compliance, the employees, business partners and consultants of the Company could take actions that violate applicable anticorruption laws or regulations. Violations of these laws, or allegations of such violations, could result in loss, reduction or expropriation and/or have a material adverse effect on the Company's business, results of operations or financial condition. The Company's international efforts may not produce desired levels of sales. If and when the Company enters into new markets in the future, it may experience different competitive conditions and/or different customer requirements. As a result, the Company may be less successful than expected in expanding sales in its future targeted international markets. Sales into new international markets may take longer to ramp up and reach expected sales and profit levels, or may never do so, thereby affecting the Company's overall growth and profitability. To build brand awareness in these new markets, the Company may need to make greater investments in legal compliance, advertising and promotional activity than originally planned, which could negatively impact the expected profitability of sales in those markets. These or one or more of the other factors listed above may harm the Company's business, results of operations or financial condition.

The Company will continue to monitor developments and policies in the emerging markets in which it will operate and assess the impact thereof to its operations, however such developments cannot be accurately predicted and could have an adverse effect on the Company's operations or profitability.

# Reliance on Licenses and Authorizations

The Company's ability to grow, process, store, export and sell psilocybin mushrooms and psilocybin mushroom products in the Kingdom of Lesotho is dependent on the Company's ability to sustain or obtain the necessary licenses and authorizations by certain government authorities in the Kingdom of Lesotho, including, but not limited to, its current licence, the Mind Health Lesotho Permit. The licenses and authorizations are subject to ongoing compliance and reporting requirements, and the ability of the Company to obtain, sustain or renew any such licenses and authorizations on acceptable terms is subject to changes in regulations and policies and to the discretion of the applicable authorities or other governmental agencies in foreign jurisdictions.

Failure to comply with the requirements of the licenses or authorizations or any failure to maintain the licenses or authorizations in Lesotho would have a material adverse impact on the business, financial condition and operating results of the Company. Although the Company believes that it will meet the



requirements to obtain, sustain or renew the necessary licenses and authorizations, there can be no guarantee that the applicable authorities will issue or renew these licenses or authorizations (as the case may be). Should the authorities fail to issue or renew the necessary licenses or authorizations, the Company may be curtailed or prohibited from the production or distribution of psilocybin mushrooms or from proceeding with the development of its operations as currently proposed and the business, financial condition and results of the operation of the Company may be materially adversely affected.

There is currently no Jamaican legislation which specifically regulates psilocybin, or psilocybin containing mushrooms in the way that, for example, cannabis is regulated in Jamaica. Due to the ceasing of operations in the territory, the developments in Jamaican legislation shall remain monitored by the Company. Please refer to "*Regulatory Framework and Licensing Regime – Jamaica*" above for more information, which section has been included for information purposes.

# Negative Results from Clinical Trials

From time to time, studies or clinical trials on medical-grade psilocybin mushroom products may be conducted by academics, research institutions or others, including government agencies. The publication of negative results of studies or clinical trials related to the Company's proposed products or the therapeutic areas in which the Company's proposed products will compete could have a material adverse effect on the Company's sales.

# Serious adverse events or other safety risks

If any of Psyence's current or future drug candidates, prior to or after any approval for commercial sale, cause serious or unexpected side effects, or are associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, for example, regulatory authorities may interrupt, delay or halt clinical trials, regulatory authorities may deny regulatory approval of future drug candidates or Psyence could be sued and held liable for harm caused to patients. Any of these events could prevent us from achieving or maintaining market acceptance of our drug candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

# Research and Development Project Implementation

There is no guarantee that the Company's intended project implementation timelines will be met as anticipated, or at all. The failure to achieve these milestones and deliverables could negatively impact the Company's ability to raise additional funds required to fund its ongoing operations and research and development initiatives, ultimately impacting the financial viability of the Company. There is also no guarantee that the Company's research and development efforts will result in commercially viable products, suitable for registration with the necessary authorities.

# Health Canada Regulations

If the Company decides to conduct any future research in Canada into products that involve ingredients that are controlled under the CDSA (including certain psychedelics such as psilocybin) it will require a research license or Section 56 Exemption from Health Canada with similar controlled substance authorizations required from a federal, competent authority in other jurisdictions. There is no assurance that such exemption would be granted, and if it were not to be granted, it might prevent the Company from handling and researching such products in Canada without collaborating with a licensed partner.

# The Expansion of the Use of Psychedelics in the Medical Industry may require New Clinical Research

Research in Canada and internationally regarding the medical benefits, viability, safety, efficacy, addictiveness, dosing and social acceptance of psychedelic and psychoactive products derived from psilocybin remains in early stages. There have been relatively few clinical trials on the benefits of such products. Although the Company believes that the articles, reports and studies support its beliefs



#### PSYENCE GROUP INC. Management's Discussion and Analysis

regarding the medical benefits, viability, safety, efficacy, dosing and social acceptance of psychedelic and psychoactive products derived from psilocybin, future research and clinical trials may prove such statements to be incorrect, or could raise concerns regarding, and perceptions relating to, psychedelic and psychoactive products derived from psilocybin. Given these risks, uncertainties and assumptions, readers should not place undue reliance on such articles and reports. Future research studies and clinical trials may draw opposing conclusions to those stated in this MD&A or reach negative conclusions regarding the medical benefits, viability, safety, efficacy, dosing, social acceptance or other facts and perceptions related to psychedelic and psychoactive products derived from psilocybin, which could have a material adverse effect on the demand for the Company's products/compounds with the potential to lead to a material adverse effect on the Company's business, financial condition and results of operations.

# Competition from Other Companies

An increase in the companies competing in this industry could limit the ability of the Company to expand its operations. Current and new competitors may have better capitalization, a longer operating history, more expertise and be able to develop higher quality equipment or products at the same or a lower cost. The Company cannot provide assurances that it will be able to compete successfully against current and future competitors. Competitive pressures faced by the Company could have a material adverse effect on its business, operating results and financial condition.

# Unfavourable Publicity or Consumer Perception

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

# Development of the Business of the Company

The development of the business of the Company and its ability to execute on its expansion opportunities described herein will depend, in part, upon the amount of additional financing available. Failure to obtain sufficient financing may result in delaying, scaling back, eliminating or indefinitely postponing expansion opportunities and the business of the Company's current or future operations. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be acceptable to the Company. In addition, there can be no assurance that future financing can be obtained without substantial dilution to existing shareholders.



# The Company expects to incur significant ongoing costs and obligations related to its investment in infrastructure, growth, regulatory compliance and operations

The Company expects to incur significant ongoing costs and obligations related to its investment in developing its business and the products, which could have a material adverse impact on the Company's results of operations, financial condition and cash flows. In addition, future changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Company's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of the Company. The Company's efforts to grow its business may be costlier than the Company expected, and the Company may not be able to increase its revenue enough to offset its higher operating expenses. The Company may incur significant losses in the future for a number of reasons, including the other risks described in this MD&A, unforeseen expenses, difficulties, complications and delays, and other unknown events. If the Company is unable to achieve and sustain profitability, the market price of the common shares may significantly decrease.

# Inability to Innovate

In the area of innovation, the Company must be able to develop new products that appeal to customers. This depends, in part, on the technological and creative skills of its personnel and on its ability to register and protect its intellectual property rights.

# Personnel

The Company has a small management team, and the loss of any key individual could affect the Company's business. Additionally, the Company will be required to secure additional personnel to facilitate its marketing and product development initiatives. Any inability to secure and/or retain appropriate personnel may have a materially adverse impact on the business and operations of the Company.

#### The Continued Development of the Company and its Business will require Additional Financing

The failure to raise additional capital could result in the delay or indefinite postponement of current business objectives or the Company going out of business. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be favourable to the Company.

# If additional funds are raised through issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of holders of common shares

The Company's articles permit the issuance of an unlimited number of common shares, and shareholders will have no pre-emptive rights in connection with such further issuance. The directors of the Company have discretion to determine the price and the terms of issue of further issuances. Moreover, additional common shares will be issued by the Company on the exercise of options under the Company option plan and restricted share units under the Company restricted share unit plan,,and upon the exercise of the Company's outstanding warrants. In addition, from time to time, the Company may enter into transactions to acquire assets or shares of other companies. These transactions may be financed wholly or partially with debt, which may temporarily increase the Company's debt levels above industry standards. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Company to obtain additional capital and to pursue business opportunities, including potential acquisitions.



# Risk Factors Related to the Proposed Business Combination with Newcourt

The proposed business combination with Newcourt is subject to a number of conditions to closing including among others: a minimum cash requirement, obtaining Newcourt and PBC shareholder approval; the completion of regulatory review from the SEC and the CSE; the filing effectiveness of the registration statement; obtaining required consents or approvals; and the resignation of certain Newcourt's directors and officers.

In addition, the consummation of the business combination is subject to the parties being satisfied with their due diligence of the other parties, any conditions that the CSE may impose, including, if required, approval from the Company shareholders, and is also predicated on the parties settling and executing a number of ancillary agreements.

In connection with the Business Combination (and assuming redemptions of shares by its public stockholders) the parties seek to secure additional financing via a private placement that, if obtained, would result in additional cash proceeds, such that a minimum of USD\$20 million in cash will be held in trust by Newcourt. Failure to secure such additional funding places the consummation of the Business Combination at risk and will result in wasted costs on the part of the Company.

#### Developing laws and enactment of new regulations governing psilocybin-containing products

The success of Psyence's drug candidates and future approved products, if any, is subject to a number of constantly evolving state and federal laws, regulations, and enforcement policies pertaining to psilocybin containing products. Local, state, federal, and international psilocybin laws and regulations remain highly restrictive and subject to evolving interpretations, which could require Psyence to incur substantial costs associated with compliance requirements. In addition, it is possible that regulations may be enacted in the future that will be directly applicable to Psyence's proposed business regarding the administration of psilocybin or psilocybin-assisted psychotherapy. Psyence cannot predict the nature of any future laws, regulations or administrative policies and procedures, when and if promulgated, could have on its activities in the psychedelics industry. There can be no assurance that Psyence's drug candidates containing psilocybin (as the active pharmaceutical ingredient) will be approved for commercialization in Australia, the US or any other target jurisdiction at any time in the near or distant future. Any regulations the FDA issues relating to the sale, marketing, and/or other activities involving administration of psilocybin or psilocybin or psilocybin-assisted psychotherapy could have a material adverse effect on Psyence's business, financial condition and results of operations.

#### Change in Laws, Regulations and Guidelines

The cultivation, processing, manufacturing, packaging, labeling, advertising and distribution of the Company's planned products is subject to regulation by one or more governmental authorities, and various agencies of the federal, provincial, state and localities in which the Company's products are sold. These government authorities may attempt to regulate any of its products that fall within their jurisdiction. Such governmental authorities may not accept the evidence of safety for any ingredients that the Company may want to market, may determine that a particular product or product ingredient presents an unacceptable health risk and may determine that a particular statement of nutritional support that the Company wants to use is an unacceptable claim. Such a determination would prevent the Company from marketing particular products or using certain statements of nutritional support on its products. The Company also may be unable to disseminate third-party literature that supports its products if the third-party literature fails to satisfy certain requirements. In addition, government authorities could require the Company to remove a particular product from the market. Any recall or removal would result in additional costs to the Company, including lost revenues from any products that it is required to remove from the market, any of which could be material. Any such product recalls or removals could lead to liability, substantial costs and reduced growth prospects, all of which could be material.



# Regulatory Authority – Lesotho and South Africa

Lesotho's government and regulatory bodies wield broad powers and authority to issue, alter, or revoke licenses and permits which are vital to the Company's business operations in the country. There is also a corresponding lack of well-established and independent processes to appeal regulatory or government actions that are unfavourable to the Company's business operations. Therefore, the Company's operations are subject to risks associated with obtaining and maintaining licenses and permits from appropriate governmental authorities. The Ministry of Health has established a Narcotics Bureau, the LNB, which supports and assists in the issuance of licences and permits. There is no assurance that such licenses and permits can be obtained, renewed or re-registered, as applicable, or that delays will not occur in obtaining all necessary licenses and permits or renewals of such licenses and permits. Any failure to obtain or maintain the necessary licenses and permits will have a material adverse impact on the Company and its business, assets, financial condition, results of operations and prospects.

Good Psyence's operations in South Africa involve the trade of products which do not contain any psilocybin or any other controlled substance under the narcotics laws of South Africa, and are otherwise not regulated under the Medicines Act. However, should SAHPRA determine that the GOODMIND<sup>™</sup> products are in fact "complementary medicines" or "health supplements" as defined in the Medicines Act, such products and operations will fall under the supervision and control of SAHPRA and the Minister of Health (South Africa), who may release further guidelines on the regulation of complementary medicines/health supplements resulting in additional licences and product, manufacturing and quality standards that more closely resemble those associated with more regulated medicines.

# Crime and Business Corruption Risk – Lesotho and South Africa

The Company conducts business in Lesotho which has experienced high levels of business corruption. Transparency International ranks Lesotho 99<sup>th</sup> out of 180 countries in the 2022 Corruption Perceptions Index. The Company has a joint venture selling nutraceutical products in South Africa (GOODMIND<sup>™</sup>). Transparency International ranks South Africa as 72<sup>nd</sup> out of 180 countries in the 2022 Corruption Perceptions Perceptions Index.

The Company and its personnel are required to comply with applicable anti-bribery laws, including the Canadian Corruption of Foreign Public Officials Act, as well as local laws in all areas in which the Company does business. These, among other things, include laws in respect of the monitoring of financial transactions and provide a framework for the prevention and prosecution of corruption offences, including various restrictions and safeguards. However, there can be no guarantee that these laws will be effective in identifying and preventing money laundering and corruption. The failure of some of the governments where the Company does business to fight corruption or the perceived risk of corruption could have adverse effects on the local economies. Any allegations of corruption or evidence of money laundering in those countries could adversely affect the ability of those countries to attract foreign investment and thus have adverse effects on its economy which in turn could have adverse effects on the Company's business, results of operations, financial condition and prospects. Moreover, findings against the Company, the directors, the officers or the employees of the Company, could result in criminal or civil penalties, including substantial monetary fines, against the Company, the directors, the officers or the employees of the Company. Any government investigations or other allegations against the Company, the directors, the officers or the employees of the Company, or finding of involvement in corruption or other illegal activity by such persons, could significantly damage the Company's reputation and its ability to do business.

#### Enforceability of Foreign Judgements – Lesotho and South Africa

A foreign judgment is not directly enforceable in Lesotho, however foreign judgments may be placed before a court in Lesotho for it to be recognised domestically and thereafter enforced in Lesotho as a judgement of the High Court of Lesotho.



Foreign judgments can be enforced domestically by making use of the common law or in terms of the Reciprocal Enforcement of Judgments Proclamation No. 2 of 1922. In terms of this Act, judgments obtained in the High Courts of England, Ireland, or Scotland can be enforced by use of the Proclamation. The Proclamation has been extended to include Botswana, Swaziland, Zimbabwe, Zambia, Tanzania, Malawi, Kenya New Zealand, Australia, and Uganda.

Foreign awards are dealt with in terms of the New York Convention. The High Court of Lesotho has competent jurisdiction in respect of foreign awards. Furthermore, an application for recognition and enforcement would require a court order to declare such an award enforceable. The Company cannot guarantee that a judgement in Canada will be enforced in Lesotho.

The enforcement of foreign judgments in South Africa is governed by the common law. In general, one must file an application with the High Court or alternatively, one can proceed by provisional sentence summons. The following will, *inter alia*, need to be alleged and proved in order to enforce a foreign judgment in South Africa:

- 1. The foreign court must have had jurisdiction to adjudicate the principle case;
- 2. The judgment must be final and not subject to appeal or have been superannuated;
- 3. The enforcement must not be contrary to South African public policy; and
- 4. The judgment cannot be for penalties or fines imposed by a foreign state.

#### Limited Market for Securities

The common shares are listed on the CSE and traded on the OTCQB, however, there can be no assurance that a continued active and liquid market for the common shares will be maintained.

#### No Operating History

The Company is an early-stage enterprise and 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. The Company has no history in the psilocybin mushroom cultivation industry before May 2020 and no history of operations or earnings, save for the earnings derived from the sale of the GOODMIND<sup>™</sup> products.

The Company is therefore subject to many of the risks common to entering a new area of investment, including under-capitalization, 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 its investment and the likelihood of success must be considered in light of the Company's lack of experience in this industry.

Because the Company has limited operating history in an emerging area of business, readers should consider and evaluate its operating prospects in light of the risks and uncertainties frequently encountered by early-stage companies in rapidly evolving markets.

These risks may include:

- risks that it may not have sufficient capital to achieve its growth strategy;
- risks that it may not develop its product and service offerings in a manner that enables it to be profitable and meet its customers' requirements;
- risks that its growth strategy may not be successful;
- risks that fluctuations in its operating results will be significant relative to its revenues; and
- risks relating to an evolving regulatory regime.



The Company's growth will depend substantially on its ability to address these, and the other risks described in this section. If it does not successfully address these risks, its business may be significantly harmed.

# Consequences of Violations of Laws and Regulations

In Canada, certain active ingredients such as psilocybin are classified as controlled substances and are listed on Schedule III of the CDSA. As such, possession and use of these substances is prohibited unless approved. The governmental authorities in Canada may allow for exemptions to parties to allow possession of controlled substances for scientific purposes or on compassionate grounds in the case of end-of-life treatment. Further, a dealer's license can be obtained under the Food and Drugs Regulations allowing for the transport, manufacturing, processing and sale of products containing a controlled substance like psilocybin in certain circumstances. Programs relating to controlled substances are strict and penalties for contravention of these laws could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings initiated by either government entities in the jurisdictions in which the Company may in the future operate, or private citizens or criminal charges. The Company's current plans with respect to psilocybin are limited to conducting scientific research and development in compliance with applicable laws in the jurisdictions in which the Company is conducting business. Currently, the Company has no plans to sell psilocybin mushroom products in Canada, however, it is exploring the potential to conduct research with respect to psilocybin in Canada with a duly licenced partner, subject to approvals by all applicable regulatory agencies. There is no guarantee that the Company would be able to obtain an exemption under the CDSA or a dealer's licence under the Food and Drugs Regulation, which would prevent the Company from being able to handle or research those substances in Canada without collaborating with a licensed partner. The Company will apply for an exemption under the CDSA or a dealer's licence under the Food and Drugs Regulation if the Company decides to offer its psilocybin products or conduct research in Canada. The Company does not intend to apply for the aforementioned within the next 12 months. During this process, the Company will seek advice from experts in Canadian food and drugs regulation.

# Production and Processing Facility

The Company may incur expenditures toward the improvement and maintenance of its production and processing facility in Lesotho. Adverse changes to the Company's leased premises in Lesotho including, but not limited to, amendments to the lease, environmental and climate change, and restrictions to expansion could have a materially adverse effect on the operations of the Company.

# <u>The Company's actual financial position and results of operations may differ materially from the expectations of the Company's management</u>

The Company's actual financial position and results of operations may differ materially from management's expectations. As a result, the Company's revenue, net income and cash flow may differ materially from the Company's internally projected revenue, net income and cash flow. The process for estimating the Company's revenue, net income and cash flow requires the use of judgement in determining the appropriate assumptions and estimates. These estimates and assumptions may be revised as additional information becomes available and as additional analyses are performed. In addition, the assumptions used in planning may not prove to be accurate, and other factors may affect the Company's financial condition or results of operations.

# The Company may become subject to litigation

The Company's participation in the medical-grade psilocybin mushroom industry and nutraceuticals market may lead to litigation, formal or informal complaints, enforcement actions and inquiries by third parties, other companies or various governmental authorities against the Company. Litigation, complaints and enforcement actions involving the Company could consume considerable amounts of



financial and other corporate resources, which could have an adverse effect on the Company's future cash flows, earnings, results of operations and financial condition.

# <u>The Company may be forced to litigate to defend its intellectual property rights, or to defend against claims by third-parties against the Company relating to intellectual property rights</u>

The Company may be forced to litigate to enforce or defend future intellectual property rights, to protect its trade secrets or to determine the validity and scope of other parties' proprietary rights. Any such litigation could be very costly and could distract its management from focusing on operating the Company's business. The existence or outcome of any such litigation could harm the Company's business. Further, because the content of much of the Company's intellectual property concerns medical-grade psilocybin mushroom and other activities that are not legal in some state jurisdictions or under federal law, the Company may face additional difficulties in defending its intellectual property rights.

The Company is further dependent, to an extent, on Filament to maintain and defend the intellectual property being licensed to the Company under the Filament Licensing Agreements, and which is relevant for use in the Company's approved UK palliative care clinical trial and proposed Australian palliative care clinical trial (please see the paragraphs above titled Licensed Intellectual Property, and Palliative Care Clinical Trial for more information). Any failure on the part of Filament to adequately maintain or defend its intellectual property will have a direct effect on the viability of the Company's UK and Australian palliative care clinical trial initiatives.

# Insurance Coverage

The Company's business is subject to a number of risks and hazards generally, including adverse environmental conditions, accidents, product liability and changes in the regulatory environment. Such occurrences could result in damage to assets, personal injury or death, environmental damage, delays in operations, monetary losses and possible legal liability. Although the Company maintains insurance to protect against certain risks in such amounts as it considers to be reasonable, its insurance does not cover all the potential risks associated with its operations. The Company may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. Moreover, insurance against risks such as environmental pollution or other hazards encountered in the operations of the Company is not generally available on acceptable terms. The Company might also become subject to liability for pollution or other hazards which may not be insured against or which the Company may elect not to insure against because of premium costs or other reasons. Losses from these events may cause the Company to incur significant costs that could have a material adverse effect upon its financial performance and results of operations.

# Ability to establish and maintain bank accounts

While the Company does not anticipate dealing with banking restrictions, there is a risk that banking institutions in countries where the Company operates will not accept payments related to the psilocybin mushroom industry. Such risks could increase costs for the Company. The Company's inability to manage such risks may adversely affect the Company's operations and financial performance.

# Product Liability

The Company intends to produce products designed to be ingested by humans and will therefore face a risk of exposure to product liability claims, regulatory action and litigation if its products are alleged to have caused bodily harm or injury. In addition, the sale of consumable products involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Section 61 of the South African Consumer Protection Act, No. 68 of 2006 ("**CPA**") establishes strict liability within the context of defective products distributed in South Africa. A producer, importer, distributor or retailer of any goods must comply with the CPA and can be liable for any harm, irrespective of whether the harm



resulted from negligence, meaning that a producer or importer, distributor or retailer of any goods are liable for defective or hazardous products.

Adverse reactions resulting from human consumption of medical-grade psilocybin mushroom products alone or in combination with other medications or substances could occur. The Company could therefore be subject to various product liability claims, including, among others, that its products caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning health risks, possible side effects or interactions with other substances. A product liability claim or regulatory action against the Company could result in increased costs, could adversely affect the Company and could have a material adverse effect on its results of operations and financial conditions.

# Pathway to Registration of Complementary Medicines

The Company's GOODMIND<sup>™</sup> products, launched via Good Psyence, are classified as foodstuffs, however, there can be no guarantee that South African medicines and health regulator, SAHPRA, will agree with such classification. Should SAHPRA determine that the GOODMIND<sup>™</sup> products are in fact "complementary medicines" or "health supplements" as defined in the Medicines Act, and issue a call-up notice for registration, Good Psyence will be required to follow the registration process set out in the Roadmap and adhere to the deadlines imposed by SAHPRA. Please refer to "*Regulatory Framework and Licensing Regime – South Africa - Health supplements and complementary medicines*" above for more information.

# If the Company is unable to attract and retain key personnel, it may not be able to compete effectively

The Company will depend upon its ability to attract and retain key management, including the Company's directors, officers and technical experts. The Company will attempt to enhance its management and technical expertise by continuing to recruit qualified individuals who possess desired skills and experience in certain targeted areas. The Company's inability to retain employees and attract and retain sufficient additional employees or engineering and technical support resources could have a material adverse effect on the Company's business, results of operations, sales, cash flow or financial condition. Shortages in qualified personnel or the loss of key personnel could adversely affect the financial condition of the Company or results of operations of the business and could limit the Company's ability to develop and market its medical-grade psilocybin mushroom products. The loss of any of the Company's business plan and strategy, and the Company may not be able to find adequate replacements on a timely basis, or at all. The Company does not maintain key person life insurance policies on any of the Company's employees.

# The size of the Company's target market is difficult to quantify

As the psilocybin mushroom industry is in an early stage with uncertain boundaries, there is a lack of information about comparable companies available and, few, if any, established companies whose business model the Company can follow or upon whose success the Company can build. There can be no assurance that the market size is sufficiently large for its business to grow as projected, which may negatively impact its financial results. The Company regularly follows market research.

#### Reliance on Limited Jurisdictions

To date, the Company's active activities and resources have been primarily focused in Southern Africa (for research and development). The Company expects to continue the focus on expansion opportunities into other jurisdictions including Canada, Australia and the United Kingdom. Adverse changes or developments within Southern Africa could have a material and adverse effect on the Company's ability to continue its business, financial condition and prospects. Additionally, any material or adverse change in jurisdictions in which the Company will do business may affect the Company's ability to continue producing medical-grade psilocybin mushroom products, its business, financial condition and prospects.



# No guarantee on the use of available funds by the Company

The Company cannot specify with certainty the particular uses of its available funds. Management has broad discretion in the application of its available funds. Accordingly, shareholders will have to rely upon the judgment of management with respect to the use of available funds, with only limited information concerning management's specific intentions. The Company's management may spend a portion or all of the available funds in ways that the Company's shareholders might not desire, that might not yield a favourable return and that might not increase the value of a shareholder's investment. The failure by management to apply these funds effectively could harm the Company's business. Pending use of such funds, the Company might invest available funds in a manner that does not produce income or that loses value.

# Currency Fluctuations

Recent events in the global financial markets have been coupled with increased volatility in the currency markets. Fluctuations in the exchange rate between the Canadian dollar, the Lesotho Loti, and the South African Rand may have a material adverse effect on the Company's business, financial condition and operating results. The Company may, in the future, establish a program to hedge a portion of its foreign currency exposure with the objective of minimizing the impact of adverse foreign currency exchange movements. However, even if the Company develops a hedging program, there can be no assurance that it will effectively mitigate currency risks.

# Environmental, Health and Safety Laws

The Company is subject to environmental, health and safety laws and regulations in each jurisdiction in which the Company operates. Such regulations govern, among other things, emissions of pollutants into the air, wastewater discharges, waste disposal, the investigation and remediation of soil and groundwater contamination, and the health and safety of the Company's employees. The Company may be required to obtain environmental permits from governmental authorities for certain of its current or proposed operations. The Company may not have been, nor may it be able to be, at all times in full compliance with such laws, regulations and permits. If the Company violates or fails to comply with these laws, regulations or permits, the Company could be fined or otherwise sanctioned by regulators. As with other companies engaged in similar activities or that own or operate real property, the Company faces inherent risks of environmental liability at its current and historical operational sites. Certain environmental laws impose strict and, in certain circumstances, joint and several liability on current or previous owners or operators of real property for the cost of the investigation, removal or remediation of hazardous substances as well as liability for related damages to natural resources. In addition, the Company may discover new facts or conditions that may change its expectations or be faced with changes in environmental laws or their enforcement that would increase its liabilities. Furthermore, its costs of complying with current and future environmental and health and safety laws, or the Company's liabilities arising from past or future releases of, or exposure to, regulated materials, may have a material adverse effect on its business, financial condition and results of operations.

# Management of Growth

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

# Inability to protect Intellectual Property

The Company expects to rely upon intangible and intellectual property such as copyrights, trade secrets, unpatented proprietary know-how and continuing innovation to protect the development of its



business. There can be no assurances that the steps taken by the Company to protect its intangible property and intellectual property will be adequate. To the extent that this property is infringed on, revenue could be negatively affected, and the Company may have to litigate to enforce its intangible property rights, which could result in substantial costs and divert management's attention and other resources.

# Emerging Markets Risk Factors

# Language – Lesotho and South Africa

The primary language of business in Lesotho is English, with Sesotho as a secondary language, and occasionally Afrikaans. The primary language of business in South Africa is English and occasionally Afrikaans. All employees and consultants of the Company and its subsidiaries speak English fluently. The Company has personnel available to communicate in Sesotho and Afrikaans. All business records and documents are prepared in English or translated from Sesotho or Afrikaans into English, as applicable.

# Exchange Controls, Currency Fluctuations and Credit Risks – Lesotho and South Africa

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company may be adversely affected by the fluctuations in currency exchange rates and high inflation to the extent that the Company conducts business transactions involving South African Rand or Lesotho Loti.

The currency risks associated with the local currency include the possibility of the government imposing exchange controls or limits to the availability of hard currency and other such banking restrictions. Similarly, to the extent that the Company will become involved in financial transactions with local counterparties, the Company may be exposed to credit risk on cash and cash equivalents denominated in South African Rand, or Lesotho Loti. Any such instability in currency or creditworthiness of local counterparties may have a material adverse impact on the Company.

Lesotho has adopted exchange controls governed by the Exchange Control Order No.175 of 1987, subject to Exchange Control Regulations of 1989. Authorised Dealers in Lesotho are the commercial banks mandated to enforce exchange controls. Lesotho companies may approach Authorised Dealers to obtain approval to avail of inward foreign loans and foreign trade finance facilities from any non-resident. Similarly, Lesotho companies may access trade finance, long-term loans and working capital loans in foreign currency by approaching an Authorised Dealer in this regard. Lesotho is part of the CMA, together with Namibia, South Africa and Swaziland (eSwatini). There are no foreign exchange restrictions between banks of the CMA member countries in respect of cross-border transactions amongst themselves.

South Africa has adopted exchange controls regulations similar in principle to those adopted by Lesotho. Such regulations require an additional layer of government approvals (via the South African Reserve Bank) for the flow of funds exceeding prescribed limits into and out of the country to jurisdictions outside of the CMA. All exchange control related matters must be addressed through an Authorised Dealer, which is a registered bank authorised to deal in foreign exchange or an Authorised Dealer in foreign exchange with limited authority. Non-residents may invest freely in South Africa, provided that the South African Authorised Dealer views suitable documentary evidence to ensure that the transactions are concluded at arm's length and at fair market-related prices and are financed in an approved manner. Any income earned on the investment may be transferred abroad. Approved financing includes the introduction of foreign currency, rand from a non-resident rand account in the name of the non-resident, and/or rand from a Vostro account held in the books of the Authorised Dealer. Should a non-resident disinvest from South Africa, the local sale or redemption proceeds of non-resident-owned assets in the country would be freely transferable.

These processes are largely administrative in nature but may cause delays in the transfer of monies into and out of Lesotho and/or South Africa. The Company manages its liquidity risk in these Southern



African jurisdictions by ensuring that the inward flows of funds occur by way of a loan which is approved upfront by the necessary exchange control authorities. Once the inward loan is approved, the repayment of such loans is approved and the risk that funds will not be permitted to be repatriated is extinguished.

# Foreign Exchange Risk and Liquidity – Lesotho and South Africa

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company's approach to managing liquidity is to ensure it will always have sufficient liquidity to meets its liabilities when due, under both normal and distressed conditions, without incurring unacceptable losses or risking damage to the Company's reputation. The Company's revenue streams are dependent on the overall macro-economic environment. Current and future conditions in the domestic and global economies remain uncertain. Accordingly, adverse developments in the macroeconomic environment could substantially reduce the funds spent on the products and services offered by the Company.

# Taxation Risks – Lesotho and South Africa

Lesotho's and South Africa's tax legislation and practice are in a state of continuous development and therefore are subject to varying interpretations and changes. Such interpretations of or changes in tax law may not be aligned with the Company's business interests. It is possible that the Company's ongoing operations in Lesotho and South Africa may be subject to review by Lesotho's or South Africa's respective tax authorities or be affected by changes in tax legislation or interpretation. If a party has any objection to a tax assessment granted by the Lesotho Revenue Authority, that party may appeal the tax assessment to the Commissioner General's Appeal's Committee and the Revenue Appeals Tribunal. Similarly in South Africa an appeal of a tax assessment would be through the commissioner for the South African Revenues Services.

# Licencing Regime – Lesotho and South Africa

As stated above in the paragraph titled *Regulatory Framework and Licensing Regime, Lesotho*, licencing in respect of psilocybin is governed by the DAA. Under this Act, power is delegated to the Minister of Health to exercise his discretion in promulgating regulations governing, controlling, limiting, authorizing the import into Lesotho, export from Lesotho, production, packaging, sending, transportation, delivery, sale, provision, administration, possession or obtaining of or other dealing in psilocybin. This concentration of power in one office and one Ministry is inherently risky as any deterioration in relations with the Minister of Health or the Ministry may have a material adverse impact on the Company and its business. As further stated in the paragraph titled *Regulatory Framework and Licensing Regime, Lesotho*, the Ministry of Health has established a Narcotics Bureau, the LNB, which supports and assists in the issuance of licences and permits.

To a similar extent, Good Psyence must maintain a good relationship with the South African Ministry of Health who (supported by the inspectors appointed by the Director-General in the Department of Health and SAHPRA) oversees the management and enforcement of the South African Foodstuffs Act (governing products sold for human consumption) and the Medicines Act (governing medicines, including complementary medicines and health supplements).

# Access to an Independent Judiciary – Lesotho and South Africa

In the normal course of the Company's operations, it may become involved in, named as a party to, or be the subject of various legal proceedings. Lesotho's legal system is based on UK common law and Roman-Dutch law. The Constitution provides for an independent judicial system and protects civil liberties such as freedom of speech, freedom of association, freedom of the press, freedom of assembly and freedom of religion. That being said, the Lesotho judicial system is not impervious to external social, economic, and political forces which create difficulty in predicting outcomes regarding legal matters. Judicial decisions may therefore be subject to popular or government influence which creates difficulty



in predicting outcomes regarding legal matters and may result in the Company being disadvantaged in the context of dispute resolution whether in litigation proceedings or regulatory proceedings involving tax, contractual, environmental, land rights, personal injuries, or such other disputes.

To mitigate exposure to or dependence on the domestic legal system, contracting parties usually consent by agreement to mediation, arbitration or other alternative dispute resolution mechanisms and are contractually free to elect the governing law, location and composition of the mediators and arbitrators. Arbitration in Lesotho is regulated by the Arbitration Act of 1980; however, Lesotho has also acceded to the New York Convention, without any reservations. To further mitigate commercial risks, Lesotho established a Commercial Court to improve capacity in resolving commercial cases in 2010 and as a signatory of the International Centre for Settlement of Investment Disputes, Lesotho also accepts ad hoc arbitration.

South Africa has an uncodified legal system, meaning that its laws originate from several sources including legislation, case law (court decisions), common law (based primarily on Roman-Dutch law, and influenced by UK common law), custom and indigenous laws. As a constitutional democracy, the South African Constitution (1996) provides for an independent judicial system and protects civil liberties such as freedom of speech, freedom of association, freedom of the press, freedom of assembly and freedom of religion. Furthermore, this Constitution guarantees equality before the law, providing for real equality of access to justice for every person. Special courts, such as a commercial court instituted in the Witwatersrand local division, are established to ensure speedy and effective adjudication in commercial cases. Such cases deal with matters relating to, for example, companies, mining and minerals, banking and international trade. The enforcement of foreign judgements in South Africa is permissible in the manner set out in the paragraph above *Enforceability of Foreign Judgements*.

# Differences between the Canadian Law and Applicable Provisions of the Local Laws in Lesotho and South Africa

The rights and responsibilities of the shareholders of the Company are governed by Canadian law by virtue of its incorporation under the laws of the Province of Ontario. To the extent that there may be exposure to the legal jurisdiction of Lesotho or South Africa, the rights of shareholders are generally respected in these jurisdictions. A significant number of directors and officers of the Company may be based in non-Canadian jurisdictions and most of the Company's operational assets will be located in Lesotho. Therefore, a judgement obtained in a foreign court against the Company for civil penalties may not be enforceable in Canada. Depending on the nature of the dispute, it may be possible that a Canadian court may order the enforcement of a foreign judgement in Canada; or, alternately, a court in Lesotho or South Africa may recognize a Canadian court judgement in their local jurisdiction. Refer to the paragraph titled *Enforceability of Foreign Judgements* above which expands upon this matter.

# Geographic Location – Lesotho and South Africa

Lesotho is a landlocked country within the borders of South Africa and is therefore reliant on South Africa for the shipment of goods in and out of the country. Lesotho is party to the Protocol on Trade in the South African Development Community Region and United Nations Conference on Transit Trade of Land-Locked Countries. The underlying principles of these international agreements of economic co-operation mitigate such trade risk as South Africa has pledged its commitment to helping Lesotho facilitate trade in the SADC region and internationally. South Africa has committed, in order to promote fully the economic development of land-locked countries such as Lesotho, free and unrestricted transit, in such a manner that Lesotho shall have free access to regional and international trade in all circumstances and for every type of good.

In the case of MindHealth Lesotho and its operations, the import, export and general trade regarding psilocybin is regulated by the Ministry of Health (Lesotho) under clear and enabling legislation and in accordance with a well-established import/export practice, which has been successfully implemented within the cannabis industry.



South Africa is located in the southern tip of the continent of Africa and borders Botswana, Lesotho, Mozambique, Namibia, Eswatini (Swaziland) and Zimbabwe. Despite its location, South Africa is very open to international trade, and is one of the EU's largest trading partners in Africa.

# Political Instability and Civil Unrest – Lesotho and South Africa

The government of Lesotho has been vulnerable to political instability in recent times. After taking office as the erstwhile Prime Minister of Lesotho in May 2020, Mr Moeketsi Majoro dismissed several ministers and alienated many members of parliament. In August 2022, Majoro declared a state of emergency after legislators failed to pass two crucial bills that sought to end political volatility in Parliament.

The current Lesotho Prime Minister, Sam Matekane's, position remains vulnerable as the main opposition party, the Democratic Congress (DC), recently initiated a vote of no confidence against him. Civil unrest has plagued South Africa in recent times, July 2021 specifically, which resulted in the disruption of strategic commodity supply chains and a drop in business confidence. There have not been events such as the aforementioned since July 2021. Since the bulk of the Company's South Africa products, GOODMIND<sup>™</sup>, are available for online purchase only, the Company should be less vulnerable to any future civil unrest.

# Material Contracts

The following are the material contracts, other than contracts in the ordinary course of business, and material contracts in the ordinary course of business required to be listed, that were entered into by the Company in the current financial period or prior to this period and are still in effect as of the date of this MD&A:

- The escrow agreement dated January 20, 20210 whereby securities of the Company are held in escrow by Odyssey Trust Company, as escrow agent and depositary;
- Sub-lease Agreement between Mind Health Lesotho and Highlands Pure Lesotho (then Canopy Growth Lesotho (Pty) Ltd) dated June 1, 2020;
- Loan Agreement between PBC and Mind Health Lesotho dated July 11, 2020;
- Shareholders Agreement with Goodleaf and Good Psyence governing the relationship between the parties as shareholders (in their capacities as such and among themselves) and between the shareholders (in their capacity as such) and Good Psyence;
- Intellectual Property Agreement with Goodleaf and Good Psyence governing intellectual property matters associated with the GOODMIND<sup>™</sup> brand and products;
- Mind Health Lesotho Permit;
- ISO 22000:2018 certification issued by the BSI;
- Company's new stock option plan, confirmed for adoption at the 2021 AGM;
- Amendments to the Company's existing restricted share unit plan approved at the 2021 AGM, as further amended by the Board on February 16, 2022;
- The Business Combination Agreement (as amended) concluded with Psyence, PBC and Newcourt in respect of the proposed business combination between the parties;
- Amending Agreement to the Business Combination Agreement concluded February 2023;
- The Amended and Restated Business Combination Agreement concluded on July 31, 2023;
- iNGENū MSA; and
- Filament Licensing Agreements.

Copies of these material contracts are available under the Company's SEDAR profile at <u>www.sedar.com</u>

# Additional Information

All additional information relating to the Company is available on SEDAR at www.sedar.com

