



Psyence[™] Biomedical Ltd

Investor Presentation

Nasdaq: PBM

November 2024

Forward Looking Statements

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Forward Looking Statements

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Risk Factors Relating to Psyence's Business

We are a clinical-stage biotechnology company and have incurred significant losses since our inception. We anticipate that we will incur significant losses for the foreseeable future. Psyence has a limited operating history and expects a number of factors to cause its operating results to fluctuate on an annual basis, which may make it difficult to predict the future performance of Psyence. Psyence has never generated revenue and may never be profitable. Psyence will require substantial additional funding to achieve its business goals, and if it is unable to obtain this funding when needed and on acceptable terms, it could be forced to delay, limit or terminate its product development efforts. We depend on our current key personnel and our ability to attract and retain employees. The psychedelic therapy and biotechnology industries are undergoing rapid growth and substantial change, which has resulted in an increase in competitors, consolidation and formation of strategic relationships. Acquisitions or other consolidating transactions could harm Psyence in a number of ways, including by losing strategic partners if they are acquired by or enter into relationships with a competitor, losing customers, revenue and market share, or forcing Psyence to expend greater resources to meet new or additional competitive threats, all of which could harm Psyence's operating results. Current and future preclinical and clinical studies will be conducted outside the United States, and the FDA may not accept data from such studies to support any NDAs submitted after completing the applicable developmental and regulatory prerequisites (absent an IND). There is a high rate of failure for product candidates proceeding through clinical trials. Because the results of preclinical studies and earlier clinical trials are not necessarily predictive of future results, Psyence may not have favorable results in its planned and future clinical trials. Negative results from clinical trials or studies of others and adverse safety events involving Psyence's psychedelic analogs could have a material adverse effect on Psyence's business. Costs associated with compliance with numerous laws and regulations could impact our financial results. In addition, we could become subject to increased enforcement and/or litigation risks associated with the psychedelic therapeutics industry. We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business. Our prospective products will be subject to the various federal and state laws and regulations relating to health and safety and failure to comply with, or changes in, these laws or regulations could have an adverse impact on our business. If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected. Clinical trials are expensive, time-consuming, uncertain and susceptible to change, delay or termination.

The results of clinical trials are open to differing interpretations. Psyence may be subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect Psyence's business and results of operations. Psyence may voluntarily suspend or terminate a clinical trial if at any time its believes that any of its product candidates presents an unacceptable risk to participants, if preliminary data demonstrates that the product candidate is unlikely to receive regulatory approval or unlikely to be successfully commercialized, or if sufficient funds to proceed to the next phases of clinical trials are not raised. The psychedelic therapy industry and market are relatively new, and this industry and market may not continue to exist or grow as anticipated. Negative public opinion and perception of the psychedelic industry could adversely impact Psyence's ability to operate and Psyence's growth strategy. The expansion of the use of psychedelics in the medical industry may require new clinical research into effective medical therapies. The psychedelic therapy industry is difficult to quantify and investors will be reliant on their own estimates of the accuracy of market data. Psyence may not be able to adequately protect or enforce its intellectual property rights, which could harm its competitive position. If third parties claim that intellectual property owned or used by Psyence infringes upon their intellectual property, Psyence's operating profits could be adversely affected. If Psyence is not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of its products could be significantly diminished. If we fail to meet applicable listing requirements, Nasdaq may delist our securities from trading, in which case the liquidity and market price of our securities could decline. The market price and trading volume of our securities may be volatile and could decline significantly. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of the final prospectus (File No. 333 282904) filed with the Securities and Exchange Commission on November 12, 2024 and other documents filed by the Company from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. There can be no assurance that the data contained herein is reflective of future performance to any degree. You are cautioned not to place undue reliance on forward-looking statements as a predictor of future performance as projected financial information and other information are based on estimates and assumptions that are inherently subject to various significant risks, uncertainties and other factors, many of which are beyond our control. Forward-looking statements speak only as of the date they are made, and Psyence and its respective affiliates disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of developments occurring after the date of this communication. Forecasts and estimates regarding Psyence's industry and end markets are based on sources we believe to be reliable, however there can be no assurance these forecasts and estimates will prove accurate in whole or in part. Annualized, pro forma, projected and estimated numbers are used for illustrative purpose only, are not forecasts and may not reflect actual results.

The background of the slide features a silhouette of a person's head in profile, facing left. Inside the head area, there is a detailed, textured image of a human brain. The overall color palette is a gradient of dark blues and purples, with a soft, ethereal glow.

MISSION

**To develop nature derived, psilocybin-based
therapeutics to address the unmet mental health needs
of palliative care and addiction**

Company Highlights



Phase IIb program, 25mg psilocybin in conjunction with proprietary psychotherapy, being evaluated for Adjustment Disorder in cancer in the Palliative Care context



Leveraging benefits of nature-derived psilocybin, including potential synergistic effects of similar acting molecules not present in synthetic psilocybin*



Near-term value-driving catalysts, including first patient randomized in Phase IIb trial in Australia (anticipated in Q4 2024)



Potential regulatory market and data exclusivity as a New Medicinal Entity (NME)



Acquisition of PsyLabs stake provides vertical integration to support development of second indication, Alcohol Use Disorder



Seasoned leadership team and Board with significant expertise in successful drug development

* <https://www.nature.com/articles/s41380-024-02477-w>

Psilocybin 25mg Development Programs

	Pre-clinical	Phase I	Phase II	Phase III	Projected Upcoming Milestones
Adjustment Disorder			Phase IIb		First patient enrolled – Q4'24 Top line data – 2025
Alcohol Use Disorder/ Substance Use Disorder		Protocol in Development			Initiate Phase IIb pending additional funding
Undisclosed CNS indication	2 nd Study under evaluation				Evaluation of pre-clinical data – H2'24

Psychedelics Research is Gaining Acceptance and Momentum

THE WALL STREET JOURNAL

MIND & MATTER

The New Promise of Psychedelics

Research on mice suggests that the long-banned drugs can have surprising therapeutic effects for humans, though risks remain

The New York Times

The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same.

Google co-founder backs biotech studying
psychedelic African shrub

Sergey Brin's non-profit funds research into using hallucinogen for mental health treatment



FINANCIAL TIMES

Sergey Brin is using part of the proceeds of his 2021 Tesla stake sale to invest in the start-up. © Michael Tran/AFP/Getty Images

TIME

HEALTH • DRUGS

Safer Psychedelic Drugs May Be Coming

8 MINUTE READ

The Economist

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Sensible policy on psychedelic drugs is growing more common

They show tremendous potential in treating certain mental-health disorders



The Economist

The World Ahead | The World Ahead 2023

Psychedelic medicines are expanding into the public consciousness

Magic mushrooms are just the start

Accelerating Psychedelics M&A and Growing Institutional Investor Interest



BIOTECH
Otsuka adopts new Mindset, dropping \$59M to buy Canadian psychedelic biotech



Tryp Therapeutics Inc. Announces Signing of Definitive Agreement with Exopharm Limited



BIOTECH
AbbVie inks \$2B-plus next-gen neuro deal with Gilgamesh



PSYCHEDELICS
Sales Of Johnson & Johnson Esketamine Drug Spravato Rise Nearly 100% Year Over Year



Psychedelic stock jumps as Steve Cohen's Point72 snaps up shares



Thiel-Backed Psychedelic Firm Atai to Buy Stake in Beckley

- Atai to inject \$50 million into Beckley for roughly 35% stake
- Deal to complement Atai's portfolio of psychoactive compounds

Advantages of the Development of Botanical Drugs



Differentiated FDA Pathway

Differentiated FDA Pathway with benefits as defined by the Botanical Drug Guidance (2016):

Combination of multiple active compounds

Secondary compounds are part of the API

Contrast to conventional single compound API



Intellectual property

Intellectual property advantages:

Process patents for extraction, purification and standardization

Very difficult to genericize

More similarity to biologics than to small molecules



Shorter Clinical Development

Shorter track through Clinical Development:

Large body of existing evidence of usage and safety can replace usually required preclinical studies

Historical pharmacological and pharmacodynamic studies on active compound can alleviate need for phase 1 studies



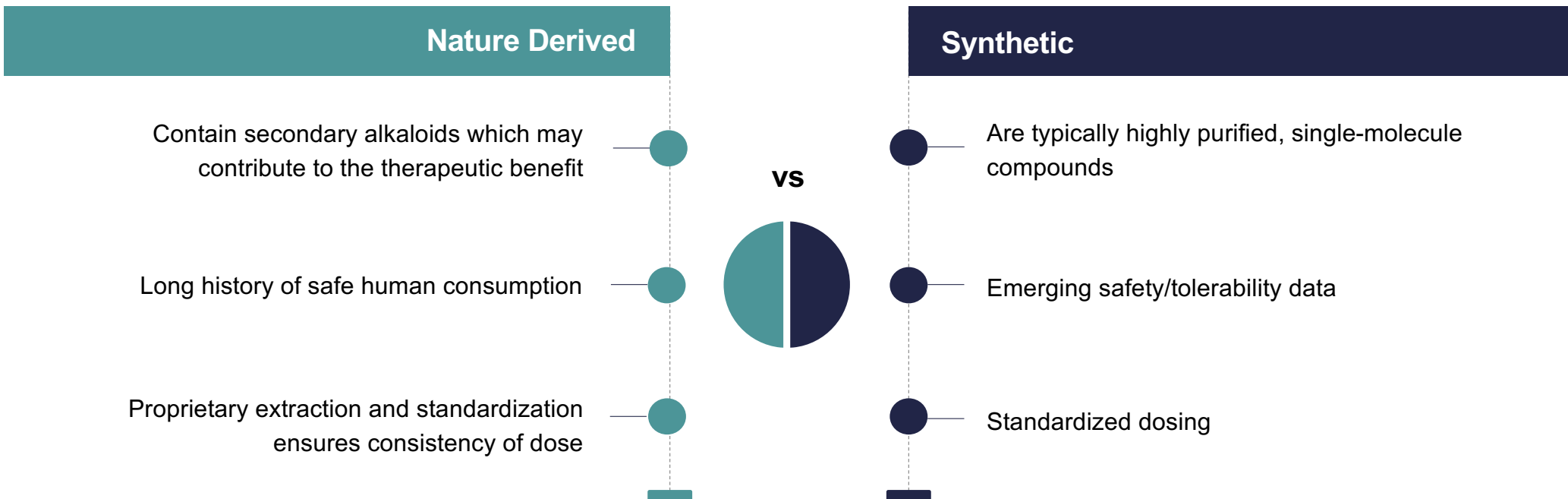
Efficacy and Consumer Preference

Entourage effect of multiple active compounds may improve efficacy and tolerability

Naturally sourced active compounds appeal to patient preferences

Nature-Derived Psilocybin vs. Synthetic Psilocybin

Psyence has licensed proprietary, patent-protected methods of extraction and standardization that may preserve the benefits of nature derived psilocybin with consistent potency ideally suited for therapeutic uses.



Nature Derived Psilocybin May Be Demonstrably More Therapeutic than Synthetic

- A recent paper published in *Molecular Psychiatry* details results of a preclinical study comparing the biological effects of nature derived psilocybin versus synthetic.
- Findings suggest that **nature derived psilocybin has a more potent and prolonged effect on neuroplasticity** than synthetic.
 - Neuroplasticity is increasingly recognized as **the gold standard** by which the efficacy of psychedelic medicines can be measured
- This evidence-based and independent finding **further validates the Psyence approach** to development of nature derived Psilocybin.

ARTICLE

OPEN

Check for updates

Effect of chemically synthesized psilocybin and psychedelic mushroom extract on molecular and metabolic profiles in mouse brain

Orr Shahrar^{1,7}, Alexander Botvinnik^{1,7}, Amit Shwartz¹, Elad Lerer^{1,2}, Peretz Golding¹, Alex Buko³, Ethan Hamid¹, Dani Kahn¹, Miles Guralnick¹, Karin Blakolmer⁴, Gilly Wolf^{1,5}, Amit Lotan⁶, Leonard Lerer^{6,6}, Bernard Lerer^{6,6} and Tzuri Lifschytz^{1,6}

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Psilocybin, a naturally occurring, tryptamine alkaloid prodrug, is currently being investigated for the treatment of a range of psychiatric disorders. Preclinical reports suggest that the biological effects of psilocybin-containing mushroom extract or “full spectrum” (psychedelic) mushroom extract (PME), may differ from those of chemically synthesized psilocybin (PSIL). We compared the effects of PME to those of PSIL on the head twitch response (HTR), neuroplasticity-related synaptic proteins and frontal cortex metabolomic profiles in male C57Bl/6j mice. HTR measurement showed similar effects of PSIL and PME over 20 min. Brain specimens (frontal cortex, hippocampus, amygdala, striatum) were assayed for the synaptic proteins, GAP43, PSD95, synaptophysin and SV2A, using western blots. These proteins may serve as indicators of synaptic plasticity. Three days after treatment, there was minimal increase in synaptic proteins. After 11 days, PSIL and PME significantly increased GAP43 in the frontal cortex ($p = 0.019$; $p = 0.039$ respectively) and hippocampus ($p = 0.015$; $p = 0.027$) and synaptophysin in the hippocampus ($p = 0.041$; $p = 0.05$) and amygdala ($p = 0.035$; $p = 0.004$). PSIL increased SV2A in the amygdala ($p = 0.036$) and PME did so in the hippocampus ($p = 0.014$). In the striatum, synaptophysin was increased by PME only ($p = 0.023$). There were no significant effects of PSIL or PME on PSD95 in any brain area when these were analyzed separately. Nested analysis of variance (ANOVA) showed a significant increase in each of the 4 proteins over all brain areas for PME versus vehicle control, while significant PSIL effects were observed only in the hippocampus and amygdala and were limited to PSD95 and SV2A. Metabolomic analyses of the pre-frontal cortex were performed by untargeted polar metabolomics utilizing capillary electrophoresis – Fourier transform mass spectrometry (CE-FTMS) and showed a differential metabolic separation between PME and vehicle groups. The purines guanosine, hypoxanthine and inosine, associated with oxidative stress and energy production pathways, showed a progressive decline from VEH to PSIL to PME. In conclusion, our synaptic protein findings suggest that PME has a more potent and prolonged effect on synaptic plasticity than PSIL. Our metabolomics data support a gradient of effects from inert vehicle via chemical psilocybin to PME further supporting differential effects. Further studies are needed to confirm and extend these findings and to identify the molecules that may be responsible for the enhanced effects of PME as compared to psilocybin alone.

Molecular Psychiatry; <https://doi.org/10.1038/s41380-024-02477-w>

Palliative Care is NOT End-of-Life (Hospice) Care

In Palliative Care, a person does not have to give up treatment that might cure a serious illness. Palliative Care can be provided along with curative treatment and may begin at the time of diagnosis

Palliative Care is*:

- Specialized medical care for people living with a life limiting illness, such as cancer or heart failure.
- Patients in Palliative Care may continue to receive treatment as well as care intended to manage their symptoms.
- Palliative Care is meant to enhance a person's current care by focusing on quality of life for them, their families and their caregivers.
- **Cancer patients receiving Palliative Care used significantly less healthcare resources, including emergency department visits, hospital admissions & inpatient days****

Palliative Care can drive significant savings for payors while improving quality of life for patients

The background of the slide features a profile of a human head facing left. Inside the head, a detailed image of a brain is visible, rendered in a light, ethereal style. The overall color palette is a gradient of blues and purples, with a soft, hazy texture.

Adjustment Disorder

Adjustment Disorder (AjD)

A global survey of psychiatrists by the WHO revealed¹:

- **AjD plays an enormous role in healthcare utilization**
- **AjD ranked 7th among 44 psychiatric categories²** they managed at least once a week in their practice
 - A second global survey of clinical psychiatrists **ranked AjD at #9²**
 - It ranked higher than **alcohol use disorder, at #8³**
- Results were largely consistent across the **44 countries on six continents** included in the survey



*According to Psyence Biomed's proprietary market research, **2.25 million people (US and EU)** with a life limiting cancer diagnosis experience distress each year⁴*

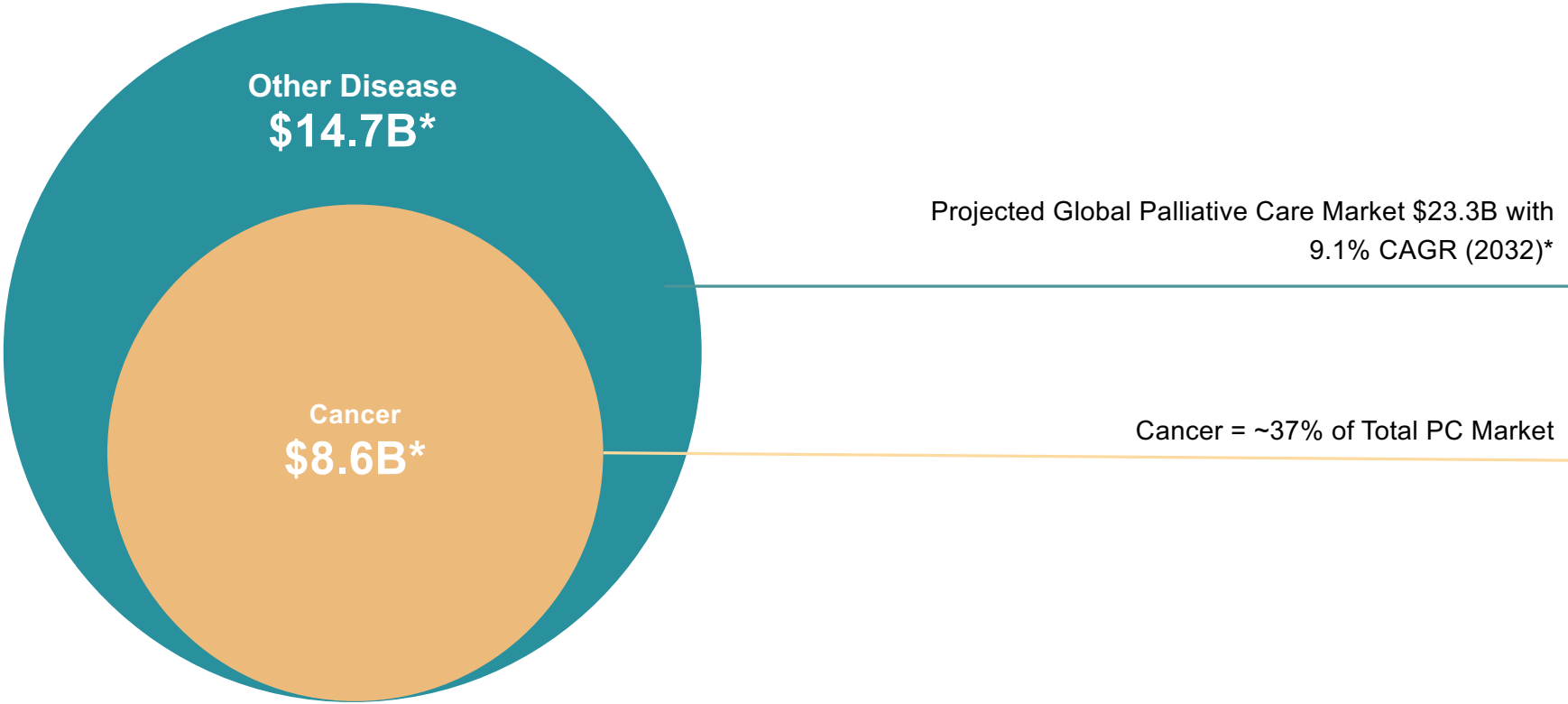
1. <https://www.tandfonline.com/doi/full/10.1080/15622975.2018.1449967?src=recsys>

2. Evans SC, Reed GM, Roberts MC, Esparza P, Watts AD, Ritchie PLJ, Maj M, Saxena S. 2013. Psychologists' perspectives on the diagnostic classification of mental disorders: results from the WHO-IUPsyS Global Survey. *Int J Psychol.* 48:177–193.

3. Reed GM, Correia JM, Esparza P, Saxena S, Maj M. 2011. The WPA-WHO global survey of psychiatrists' attitudes towards mental disorders classification. *World Psychiatry.* 10:118–131

4. From the Company's commissioned market research performed by Insight Ace Analytic in Sept. 2022

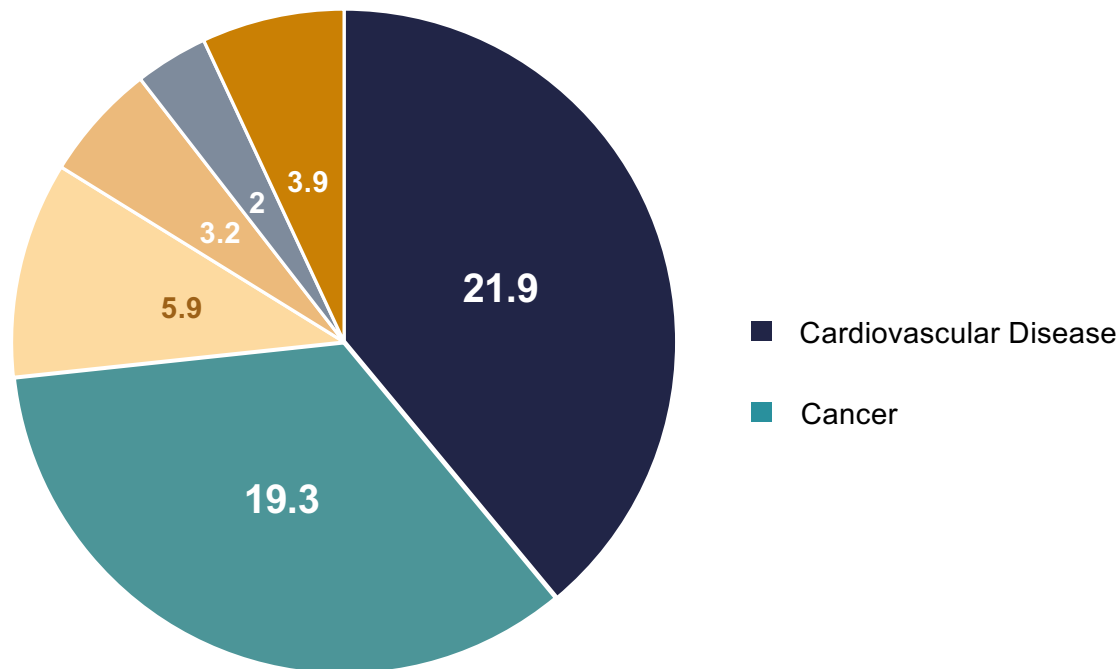
The Global Palliative Care Market is Large with a Robust Projected CAGR



*Source: <https://www.globenewswire.com/news-release/2024/10/15/2963268/0/en/Palliative-Care-Market-Projected-to-Reach-USD-23-34-Billion-by-2032-Growing-at-a-9-06-CAGR-SNS-Insider.html>

WHO Study: Worldwide, 56.8 Million People Require Palliative Care

Patients Requiring Palliative Care, Globally (millions)



34% of patients requiring palliative care – 19.3 million people – have received a **serious cancer diagnosis**

According to the WHO, “*The global need for palliative care will continue to grow as a result of the ageing of populations...*”

Only 14% of patients who require palliative care currently receive it

Patient Safety and Efficacy Enhanced by Psilocybin-Assisted Psychotherapy (PAP)



The current standard of care in most uses of psychedelic medicines for the treatment of psychiatric indications includes the provision of a supportive therapeutic context before, during, and after drug administration.*

Psyence intends to focus on the psychological distress of palliative care, an important but often ignored and/or poorly treated area. Developing our own unique PAP module to be delivered in Palliative Care

*Brennan W and Belser AB (2022), Models of Psychedelic-Assisted Psychotherapy: A Contemporary Assessment and an Introduction to EMBARK, a Transdiagnostic, Trans-Drug Model. Front. Psychol. 13:866018. doi: 10.3389/fpsyg.2022.866018

Prior Proof-of-Concept Studies Provide Strong Rationale for Upcoming Phase IIb

UCLA



JOHNS HOPKINS
UNIVERSITY



NYU

ORIGINAL ARTICLE

ONLINE FIRST

Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer

Charles S. Groh, MD; Alicia L. Danforth, MA; Gurpreet S. Chopra, MD; Marycye Hagerity, RN, BSN, MA; Charles R. McKay, MD; Adam L. Halberstadt, PhD; George R. Greer, MD

Context: Researchers conducted extensive investigations of hallucinogens in the 1950s and 1960s. By the early 1970s, however, political and cultural pressures forced the cessation of all projects. This investigation reexamines a potentially promising clinical application of hallucinogens in the treatment of anxiety reactive to advanced-stage cancer.

Objective: To explore the safety and efficacy of psilocybin in patients with advanced-stage cancer and reactive anxiety.

Design: A double-blind, placebo-controlled study of patients with advanced-stage cancer and anxiety, with subjects acting as their own control, using a moderate dose (0.2 mg/kg) of psilocybin.

Setting: A clinical research unit within a large public sector academic medical center.

Participants: Twelve adults with advanced-stage cancer and anxiety.

Main Outcome Measures: In addition to monitoring safety and subjective experience before and during experimental treatment sessions, follow-up data including results from the Beck Depression Inventory, Profile

of Mood States, and State-Trait Anxiety Inventory were collected unblinded for 6 months after treatment.

Results: Safe physiological and psychological responses were documented during treatment sessions. There were no clinically significant adverse events with psilocybin. The State-Trait Anxiety Inventory trait anxiety subscale demonstrated a significant reduction in anxiety at 1 and 3 months after treatment. The Beck Depression Inventory revealed an improvement of mood that reached significance at 6 months; the Profile of Mood States identified mood improvement after treatment with psilocybin that approached but did not reach significance.

Conclusions: This study established the feasibility and safety of administering moderate doses of psilocybin to patients with advanced-stage cancer and anxiety. Some of the data revealed a positive trend toward improved mood and anxiety. These results support the need for more research in this long-neglected field.

Trial Registration: clinicaltrials.gov Identifier: NCT00302744

Arch Gen Psychiatry. 2011;68(1):71-78.
Published online September 6, 2010.
doi:10.1001/archgenpsychiatry.2010.116

Original Paper

Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial

Roland R Griffiths^{1,2}, Matthew W Johnson¹, Michael A Carducci³, Annie Umbricht⁴, William A Richards⁵, Brian D Richards¹, Mary P Cosimano¹ and Margaret A Klinedinst¹

Abstract

Cancer patients often develop chronic, clinically significant symptoms of depression and anxiety. Previous studies suggest that psilocybin may decrease depression and anxiety in cancer patients. The effects of psilocybin were studied in 51 cancer patients with life-threatening diagnoses and symptoms of depression and/or anxiety. This randomized, double-blind, cross-over trial investigated the effects of a very low (placebo-like) dose (1 or 3 mg/70 kg) or a high dose (25 or 30 mg/70 kg) of psilocybin administered in a counterbalanced sequence with 5 weeks between sessions and a 6-month follow-up. Instructions to participants and staff minimized expectancy effects. Participants, staff, and community observers rated participant mood, attitudes, and behavior throughout the study. High-dose psilocybin produced large decreases in clinician- and self-rated measures of depressed mood and anxiety, along with increases in quality of life, life meaning, and optimism, and decreases in death anxiety. At 6-month follow-up, these changes were sustained, with about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety. Participants attributed improvements in mood and anxiety to the psilocybin treatment.

At the 6-month follow-up, these changes were sustained, with about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety.

Trial Register

clinicaltrials.gov

Identifier: NCT00302744

Arch Gen Psychiatry. 2011;68(1):71-78.

Published online September 6, 2010.

doi:10.1001/archgenpsychiatry.2010.116



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DOI: 10.1177/02998116675513
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Original Paper

Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial

Stephen Ross^{1,2,3,4,5,6}, Anthony Bossis^{1,2,4}, Jeffrey Guss^{1,2,4}, Gabrielle Agin-Lieb¹⁰, Tara Malone¹, Barry Cohen⁷, Sarah E Mennenga¹, Alexander Belser⁸, Krystallia Kaltintzi², James Babb⁹, Zhe Su³, Patricia Corby² and Brian L Schmidt²

Abstract

Background: Clinically significant anxiety and depression are common in patients with cancer, and are associated with poor psychiatric and medical outcomes. Historical and recent research suggests a role for psilocybin to treat cancer-related anxiety and depression.

Methods: In this double-blind, placebo-controlled, crossover trial, 29 patients with cancer-related anxiety and depression were randomly assigned and received treatment with single-dose psilocybin (0.3 mg/kg) or mianserin, both in conjunction with psychotherapy. The primary outcomes were anxiety and depression measured between sessions prior to the crossover at 7 weeks.

Results: Prior to the crossover, psilocybin produced immediate, substantial, and sustained improvements in anxiety and depression and led to decreases in cancer-related demoralization and hopelessness, improved spiritual well-being, and increased quality of life. At the 6.5-month follow-up, psilocybin was associated with enduring anxiolytic and antidepressant effects (approximately 60-80% of participants continued with clinically significant reductions in depression or anxiety), sustained benefits in existential distress and quality of life, as well as improved attitudes towards death. The psilocybin-induced mystical experience mediated the therapeutic effect of psilocybin on anxiety and depression.

Conclusions: In a randomized controlled trial, psilocybin produced rapid and sustained improvements in anxiety and depression in patients with life-threatening cancer.

Keywords

Psilocybin, mianserin

At the 6.5-month follow-up, psilocybin was associated with enduring anxiolytic and antidepressant effects – 60-80% of participants continued with clinically significant reductions in depression and anxiety

PEX010: Australia Clinical Trial Phase IIb

Psyence’s clinical trial program is focused on assessing the safety and efficacy of psilocybin-assisted psychotherapy for the treatment of Adjustment Disorder* due to a life-limiting cancer diagnosis versus psychotherapy alone in the Palliative Care context.

Overview	Product and Protocol	Projected Milestones		
Trial Leads Dr. Arul Sivanesan	The study protocol has been approved by the Ethics Board (HREC) using Psyence licensed product	Q1 2024 Q4 2024 2025		
Locations(s) Vitalis Research, Melbourne, EMPAX Clinic, Perth and possibly two more sites.	FDA response to Pre-IND request received	HREC ethics final approval received	HREC ethics final approval of major amendment received Oct. 24 Estimated timing of first patient randomised	Estimated top line study results
CRO Ingenu (www.ingenucro.com).	Sample size: 87 patients in three dosage arms – 1mg, 10mg and 25mg.	Countries/Sites locations: Australia (Melbourne)	Target Enrollment: 87	Drug Product / imp: PEX010 Botanical Psilocybin
Stage Phase IIb (Expected to enroll Q4 2024)	Primary endpoint: HAM-A score at ten weeks			

PEX010: Phase IIb Trial Design

Study Design:

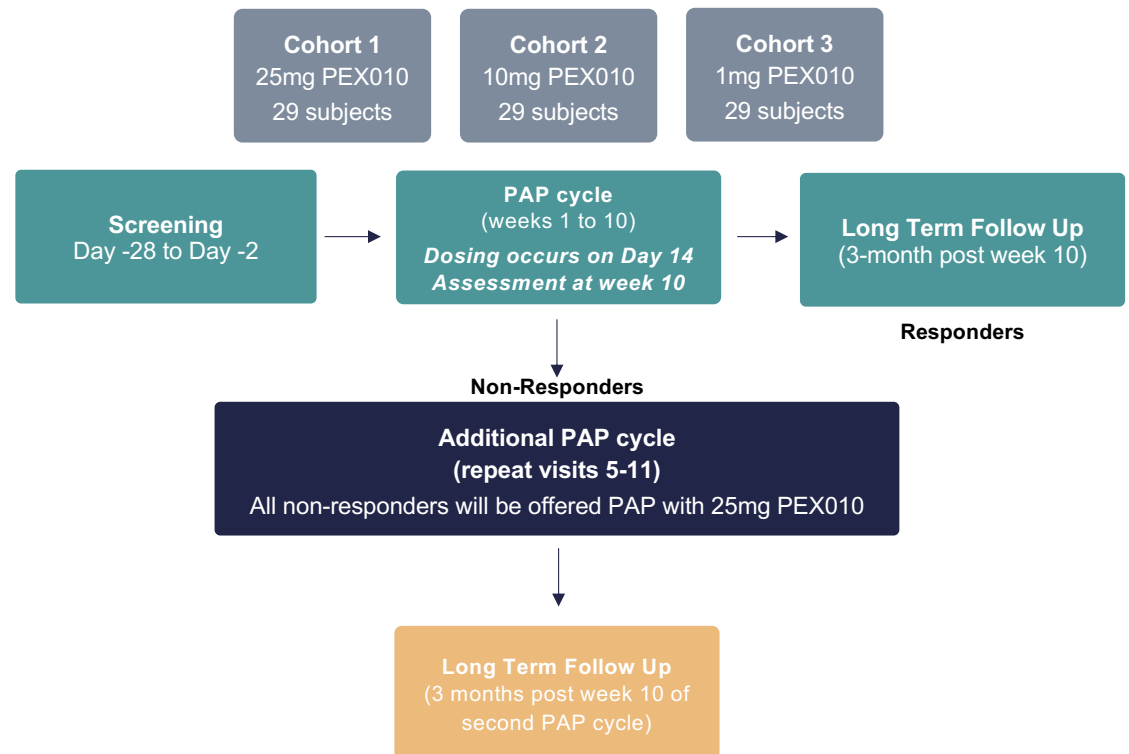
A randomized, double-blind, low-dose comparator-controlled Phase IIb study to investigate the efficacy and safety of psilocybin-assisted psychotherapy (PAP) with 25mg, 10mg and 1mg (low-dose comparator) of PEX010.

Key Inclusion Criteria:

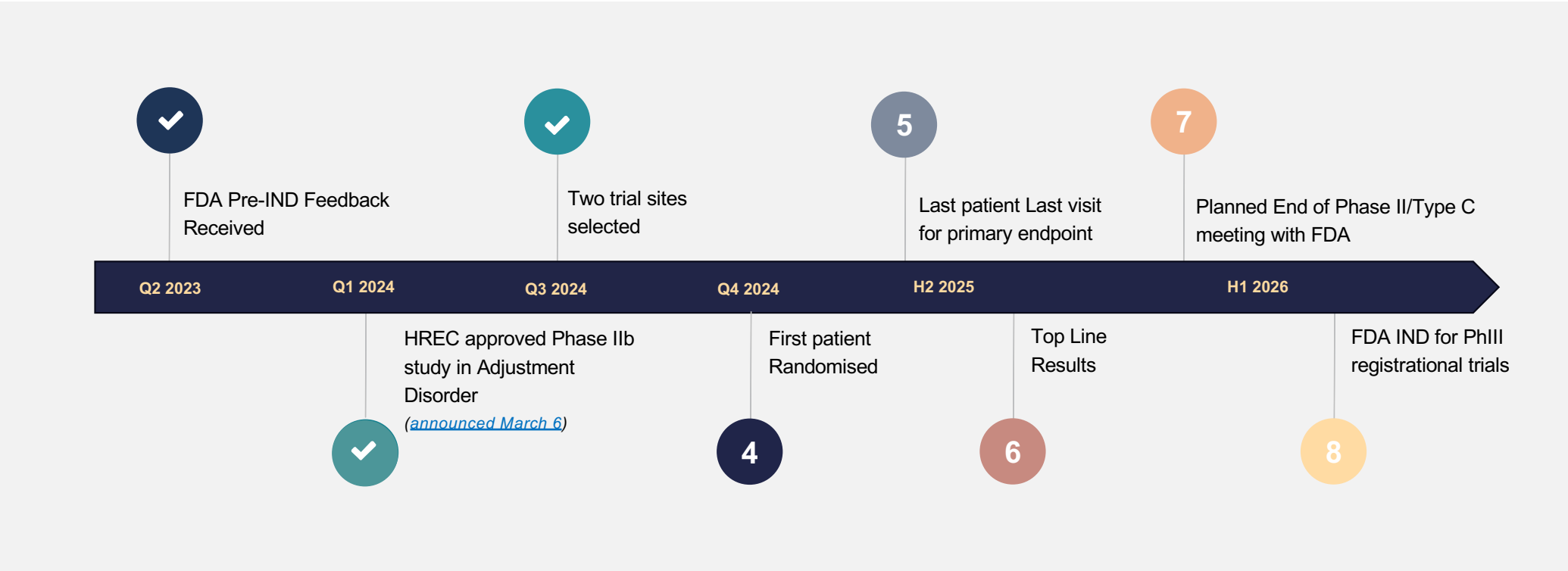
- A total of 87 subjects, aged 18-80 years
- Confirmed diagnosis of Adjustment Disorder due to incurable cancer diagnosis
- Deemed to be physically capable of undergoing a psychedelic encounter and likely to have a minimum life expectancy of one year

Endpoint:

Comparison between treatment groups in the change from baseline in the Hamilton Anxiety Rating Scale (HAM-A) total score at Week 10 after a single PAP cycle.



Anticipated Developmental Pathway to Approval¹



¹ Based on currently anticipated study recruitment rate



Alcohol Use Disorder (AUD) and Other Substance Use Disorders (SUDs)

AUD and Other SUDs: A Significant Burden to Society (US)¹

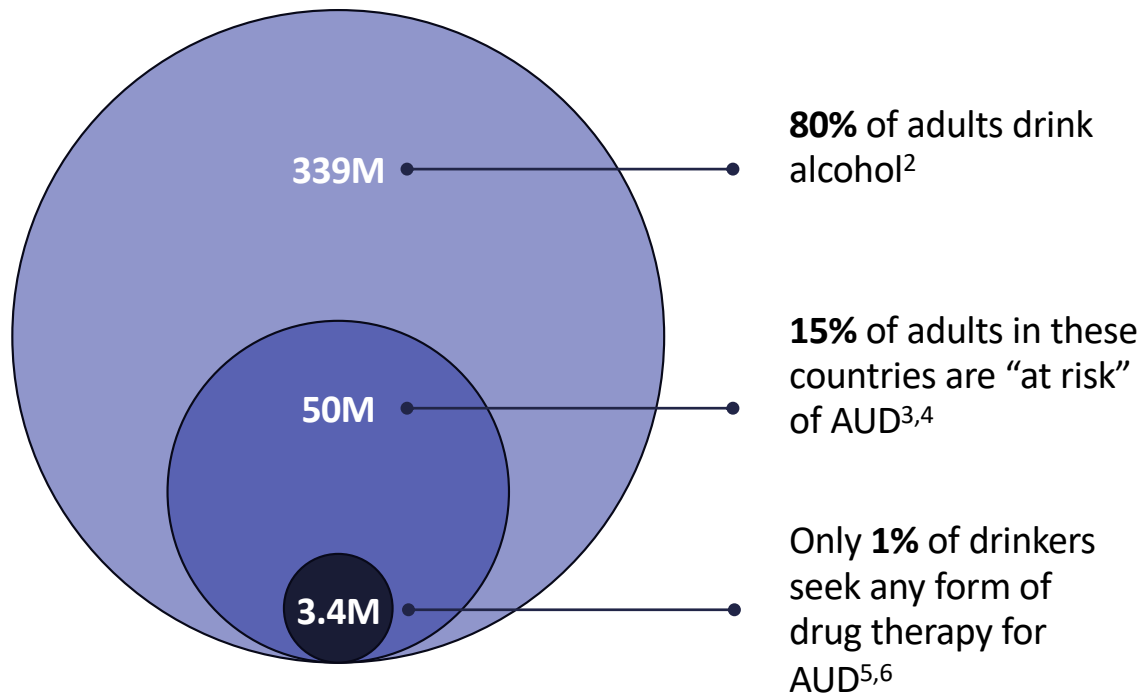


In 2022, there were over 17,000 substance abuse treatment facilities in the U.S.²

¹ Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), [2022 National Survey on Drug Use and Health \(NSDUH\), Table 5.1A](#)

² Source [HERE](#)

Alcohol is a Leading Risk Factor in the Overall Disease Burden Globally¹



Alcohol abuse and dependence have the widest treatment gap among all mental health disorders

Drug treatment efficacy is “quite modest with poor compliance”⁷

1. WHO. Global status report on alcohol and health.

2. Alcoholchange.org.uk

3. Global Alcohol Report. World Health Organization. 2018.

4. Alcohol Use Disorders. Carvalho, A.F., et al., 394: 781-792. Lancet. 2019

5. Strategies to Implement Alcohol Screening and Brief Intervention in Primary Care Settings: A Structured Literature Review. Williams EC et al. Psychol Addict Behav. 2011;25(2):206-214.

6. <https://psychedelicalpha.com/wp-content/uploads/2022/08/Morgan-Stanley-Psychedelics.pdf>

7. . Medical Treatment of Alcohol Dependence: A Systematic Review. Int J Psychiatry Med. Published online January 19, 2012.

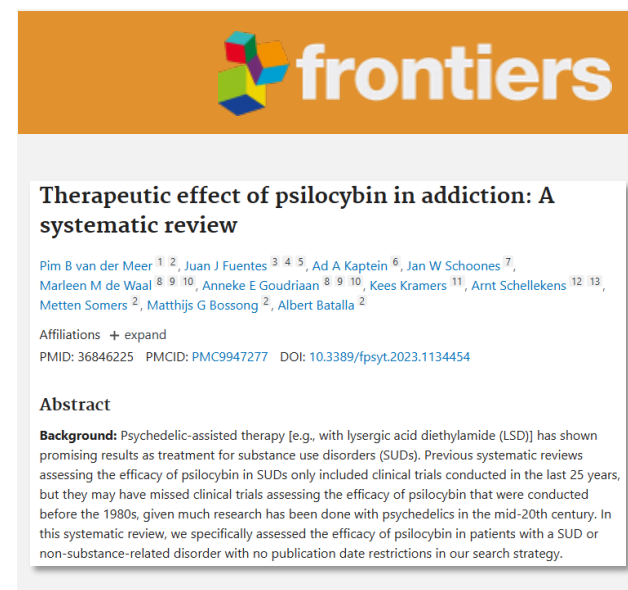
Prior Academic Studies Provide Strong Scientific Rationale for Continued Development of Psilocybin for SUDs



2022



2022



2023

A Vertically Integrated Psychedelic Biopharma Company



Strategic investment in PsyLabs transformed Psyence Biomed into a **vertically integrated** developer of psilocybin-based therapeutics

Worldwide **exclusive licensing agreement** with PsyLabs creates consistent supply of nature-derived (non-synthetic) psilocybin for Psyence Biomed's AUD clinical trial



*PsyLabs develops and produces **GMP-compliant, pharmaceutical-grade** natural psychedelics for applications in mental health and well-being*

*PsyLabs is **federally licensed** to produce psilocybin, DMT, Ibogaine and Mescaline for research, clinical trials and commercial production*

*PsyLabs' fully operational, on-site lab is **ISO22000 certified** and audited by the British Standards Institution*



Psyence's Intellectual Property within Drug development

Our intellectual property strategy is built around the following objectives:

Ensuring that we have **freedom to operate** (free of infringing third party patents) to pursue our commercial objectives in our key markets

- We conduct ongoing patent freedom to operate studies and watching searches

Establishing barriers to entry (patents and regulatory) around our key intellectual property assets

- Ensuring that we own the rights arising from our drug product development work and clinical trials
- Filing and prosecuting to grant patent applications on key novel and innovative features of our drug product development work and clinical trials
- Establishing data and market exclusivity (to the greatest extent possible) arising from a successful clinical trial



Psyence Biomed Represents a Value Driven Opportunity Versus Peer Companies ⁽¹⁾

Company	Ticker	Market Cap	Business Descriptions
GH Research PLC	NasdaqGM: GHR S	\$422m	GH Research PLC, a clinical-stage biopharmaceutical company, engages in developing various therapies to treat psychiatric and neurological disorders. The company develops 5-Methoxy-N,N-Dimethyltryptamine (5-MeO-DMT) therapies for the treatment of patients with treatment-resistant depression (TRD). Its lead program is GH001, an inhalable mebufotenin product candidate that has completed two Phase 1 clinical trials and Phase 1/2 clinical trial in patients with TRD.
COMPASS Pathways plc	NasdaqGS: CMPS	\$319m	COMPASS Pathways plc operates as a mental health care company primarily in the United Kingdom and the United States. It develops COMP360, a psilocybin therapy that is in Phase III clinical trials for the treatment of treatment resistant depression; and is in Phase II clinical trials for the treatment of post-traumatic stress disorder and anorexia nervosa.
Atai Life Sciences N.V.	NasdaqGM: ATAI	\$186m	ATAI Life Sciences N.V. develops various therapeutics to treat depression, anxiety, addiction, and other mental health disorders. Its principal clinical programs include RL-007, a pro-cognitive neuromodulator for cognitive impairment associated with schizophrenia; GRX-917, a deuterated etifoxine for anxiety disorders; VLS-01 a N,N-Dimethyltryptamine for treatment resistant depression (TRD); DMX-1002, an oral formulation of ibogaine, a cholinergic, glutamatergic and monoaminergic receptor modulator that is a naturally occurring psychedelic product isolated from a West African shrub for the treatment of opioid use disorders (OUD); and EMP-01, an oral formulation of an MDMA derivative being developed for the treatment of post-traumatic stress disorder.
MindMed	NasdaqGS: MNMD	\$495m	MindMed is a clinical-stage biopharmaceutical company developing novel product candidates to treat brain health disorders. Our mission is to be the global leader in the development and delivery of treatments that unlock new opportunities to improve patient outcomes. We are developing a pipeline of innovative product candidates, with and without acute perceptual effects, targeting neurotransmitter pathways that play key roles in brain health disorders.
Bright Minds Biosciences	NasdaqCM: DRUG	\$339m	Bright Minds Biosciences is a biotechnology company developing innovative treatments for patients with neurological and psychiatric disorders. Our pipeline includes novel compounds targeting key receptors in the brain to address conditions with high unmet medical need, including epilepsy, depression, and other CNS disorders. Bright Minds is focused on delivering breakthrough therapies that can transform patients' lives.
Cybin Inc.	NYSEAM: CYBN	\$202m	Cybin Inc., a clinical-stage biopharmaceutical company, focuses on developing psychedelic-based therapeutics. The company's development pipeline includes CYB003, a deuterated psilocybin analog, which is in Phase 1/2a clinical trial to treat major depressive and alcohol use disorders; CYB004, a deuterated dimethyltryptamine, which is in Phase 1 clinical trial for treating generalized anxiety disorders; and CYB005, a phenethylamine derivative, which in preclinical stage to treat neuroinflammation.

Source: S&P CapitalIQ, Company Filings
 1. Market data valuations reflective as of the close on 11/1/2024, the valuations listed on this slide reflect valuations of certain companies operating in a similar field as Psyence. Please note that such valuations are for informational purposes only and do not purport to reflect the real, assumed or potential valuation of the combined company. The should not be relied upon in making an investment decision with respect to the potential purchase of the combined company's securities and all individuals should refer to the disclaimers and the summary of risks related to these valuations on slides 3 and 27

Significant Unexplored White Space Exists in the Area of Nature Derived Psilocybin



Psyence Biomedical Ltd Management Team

Proven Track Record in Innovation with Extensive Pharma Development Experience

Dr. Neil Maresky
CEO



Trained MD in Emergency Medicine and Family Practice
VP Scientific Affairs AstraZeneca Canada Inc, Previously at Wyeth, Bayer
25+ years of experience leading Research and Development for Big Pharma



Dr. Clive Ward-Able
Medical Director



Pharmacist and physician with >30 years of international pharmaceutical experience in R&D and Commercialization of over 16 product launches

Experience at the executive level in global and affiliate roles for large pharmaceutical and biotechnology companies as well as smaller start-ups



Jody Aufrichtig
Executive Chairman



Chartered Accountant (ex EY) with 25 years private equity experience
Corporate governance and listed company experience

Ex Canopy Growth CEO Africa

Multiple award-winning entrepreneur and business builder creating significant shareholder value in various industries

Founded 19 companies over 25 years

Awarded Entrepreneur of the year 2023



Taryn Vos
General Counsel



Corporate and commercial attorney (associate (M&A) at Cliffe Dekker Hofmeyr Inc).

Formerly Head of Legal (AMEA) for Solar Capital (Pty) Ltd and Business Development (Legal) for Phelan Energy Group Ltd

Former Head of Legal for Canopy Growth Africa, then a subsidiary of Canopy Growth Corp



Warwick Corden-Lloyd
Chief Financial Officer



Chartered Accountant and Certified Project Manager with over 20 years of experience in the UK, the USA, and South Africa

Experienced in IPOs, capital raises, M&A, regulatory, compliance and corporate governance

Former Head of Financial Accounting at Capitec Bank

Former Senior Financial Manager at Bank of New York Mellon



Mary-Elizabeth Gifford
Chief of Global Impact



Chair of the Global Wellness Institute's Psychedelics & Healing Initiative

Joined Psyence from the DC nonprofit, The Center for Mind-Body Medicine

Co-author of the Nature vs. Synthetic Psilocybin chapter in the recent Springer Nature textbook on therapeutic mushrooms

Regularly publishes on palliative psilocybin policy issues



Psyence Biomed Board of Directors

Proven Track Record in Innovation with Extensive Operating Experience

Dr. Neil Maresky
CEO



Trained MD in Emergency Medicine and Family Practice
VP Scientific Affairs AstraZeneca Canada Inc, Previously at Wyeth, Bayer
25+ years of experience leading Research and Development for Big Pharma



Christopher Bull
Board Member



Internationally top-rated Patent and Technology Lawyer
Investor in several successful start-up businesses (Pharma, biotech, chemical processing)
Former Chairman of Venture Capital Fund and International IP firm

Jody Aufrichtig
Executive Chairman



Chartered Accountant (ex EY) with 25 years private equity experience
Corporate governance and listed company experience
Ex Canopy Growth CEO Africa
Multiple award-winning entrepreneur and business builder creating significant shareholder value in various industries
Founded 19 companies over 25 years
Awarded Entrepreneur of the year 2023



Dr. Seth Feuerstein, MD, JD
Board Member



Yale School of Medicine
Lecturer in Psychiatry
Faculty Advisor Innovation and Entrepreneurship
Assistant Clinical Professor of Psychiatry

Yale SCHOOL OF MEDICINE

Marc Balkin
Board Member



Partner, DiGame
Former Partner, Hasso Plattner Ventures
Served on investment committees of Enablis, First National Bank Vumela
FutureMaker, Alitheia IDF
Newcourt Board Member



Company Highlights



Phase IIb program, 25mg psilocybin in conjunction with proprietary psychotherapy, being evaluated for Adjustment Disorder in cancer in the Palliative Care context



Leveraging benefits of nature-derived psilocybin, including potential synergistic effects of similar acting molecules not present in synthetic psilocybin*



Near-term value-driving catalysts, including first patient randomized in Phase IIb trial in Australia (anticipated in Q4 2024)



Potential regulatory market and data exclusivity as a New Medicinal Entity (NME)



Acquisition of PsyLabs stake provides vertical integration to support development of second indication, Alcohol Use Disorder



Seasoned leadership team and Board with significant expertise in successful drug development

* <https://www.nature.com/articles/s41380-024-02477-w>