

# **OPTIMI HEALTH**

Milestones, Opportunities, and Market Landscape



#### FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements and forward-looking information within the meaning of Canadian securities legislation (collectively, "forward-looking statements") that relate to Optimi's current expectations and views of future events. Any statements that express, or involve discussions as to, expectations, beliefs, plans, objectives, assumptions or future events or performance (often, but not always, through the use of words or phrases such as "will likely result," "are expected to," "expects," "will continue," "is anticipated," "anticipates," "believes," "estimated," "intends," "plans," "forecast," "projection," "strategy," "objective," and "outlook") are not historical facts and may be forward-looking statements and may involve estimates, assumptions and uncertainties which could cause actual results or outcomes to differ materially from those expressed in such forward-looking statements. No assurance can be given that these expectations will prove to be correct and such forward-looking statements included in this news release should not be unduly relied upon. These statements speak only as of the date of this presentation. In particular and without limitation, this presentation contains forward-looking statements pertaining to activities proposed to be conducted under the Company's approved Health Canada dealer's licence and associated business related to Psilocybin, Psilocin, other psychedelic substances, some being synthetically formulated, and Optimi's plans, focus and objectives.

Forward-looking statements are based on a number of assumptions and are subject to a number of risks and uncertainties, many of which are beyond Optimi's control, which could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the impact and progression of the COVID-19 pandemic and other factors set forth under "Forward-Looking Statements" and "Risk Factors" in the Company's Annual information Form dated January 30, 2024, and other continuous disclosure filings available under Optimi's profile at www.sedar.com. Optimi undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. New factors emerge from time to time, and it is not possible for Optimi to predict all of them or assess the impact of each such factor or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement.

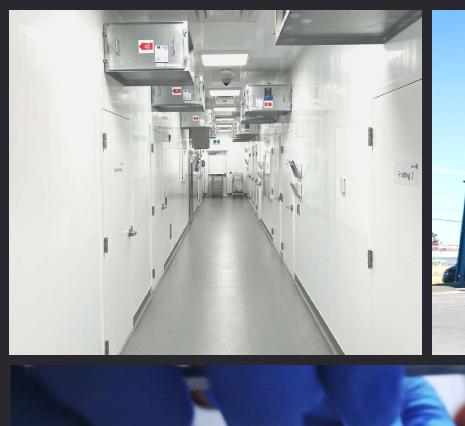
Any forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement.



Optimi is a Health Canada-approved, GMP-compliant pharmaceutical drug manufacturer specializing in the controlled substances

MDMA and botanical psilocybin.

The Company owns two 10,000-square-foot production facilities and operates under a **Drug Establishment Licence** awarded by Health Canada.









## THE OPTIMI ADVANTAGE

Two Drugs In-Market for Patient Use

Optimi has MDMA and Psilocybin capsules available to treat PTSD and TRD in Australia. Compass, Atai, Lykos and others in the industry cannot make this claim.

Years Ahead of the Competition

The competition is still in the clinical development phase, giving Optimi a significant head start on establishing sales channels and market share.

De-Risked by Comparison

While others spend hundreds of millions of dollars with no guarantees of approval, Optimi is in-market today collecting Real World Evidence and evaluating Australian Patient Outcome data for NDA submissions globally.

Future Rescheduled Market Opportunities

As countries look to follow Australia, Optimi is ready to export via their Drug Establishment Licence allowing access to patients in regulated markets.







# 2024: Key Milestones Completed

## • April 2024

Completed Validated GMP Production of 5mg Natural Psilocybin Extract Capsules with Certificate of Analysis

## • May 2024

Export Permit Issued by Health Canada for Company's First International Shipment of MDMA to Israel

## May 2024

Secured Import Certificate from Mind Med Australia for 160 Doses of MDMA & Psilocybin Capsules for Therapeutic Use in Australian Patients

#### June 2024

Health Canada Issues
Three Export Permits to
Optimi to Supply
Patients Under
Australia's Authorised
Prescriber Scheme

## May 2024

Completed Validated GMP Production of MDMA 40mg & 60mg Capsules with Certificate of Analysis

## May 2024

Phase 2 Clinical Trial Agreement for Natural Psilocybin Extract in Major Depressive Disorder with Atma Journey

### June 2024

Awarded Drug
Establishment
Licence From Health
Canada for GMP
Compliance & Global
Export for MDMA &
Psilocybin Capsules

## August 2024

Completes Inaugural Export of MDMA Capsules to Australia for PTSD Treatment

# 2024: Key Milestones Upcoming

#### June 2024

Drug Master File Submission (DMF) to Health Canada & US FDA for MDMA & Psilocybin Capsules, with stability data

#### June 2024

Export Permit Issued for Shipment of 160 Doses of MDMA & Psilocybin for Patients with PTSD & TRD to Australia

## August 2024

First Patients Dosed in Australia's Authorised Prescribers Scheme in Australia with MDMA & Psilocybin

#### • June 2024

Export Permit Issued by Health Canada for Export of Psilocybin to New Zealand for Clinical Study

## August 2024

First Cohort Dosed in Phase 2 Clinical Trial with Atma Using Natural Psilocybin to Study Major Depressive Disorder

## January 2025

Company Submits
Registration of MDMA
& Psilocybin for
Review With TGA for
Expedited Review of
150 Days Using RWE

# **MDMA** (methylenedioxy-methylamphetamine)

40mg & 60mg GMP Capsules



## Application

Manufactured for use by patients in Australia's Authorized Prescribers Scheme, as well as licensed entities conducting clinical trials around the world.

## Availability

Available in two dosages (40mg and 60mg) in hard gelatin capsule format for oral administration.

## Stability

Stable over extended periods in HDPE (High Density Polyethylene) bottles at room temperature. The API remains stable within the capsules under both real-time and accelerated storage conditions for up to three months.

#### Validation

Qualified process validation which includes the manufacturing process, and supporting processes ensuring the sanitation, equipment and environment meet or exceed GMP requirements.

## Quality

Analytical verification of identity and exceptional purity (>99%) utilizing 1H and 13C NMR spectroscopy.

## Scalability

Ability to synthesize on a multigram scale inhouse, showcasing Optimi's proficiency in largescale manufacturing.

# **PSILOCYBIN EXTRACT** (psilocybe cubensis)

### 5mg GMP Capsules & 10mg R&D Capsules



## Application

Manufactured for use in qualified patients with treatment resistant depression (TRD) within the Australian Authorized Prescribers Scheme, as well as licensed entities conducting clinical trials around the world.

## Availability

Available in a 5mg capsule format for patients in Australia via oral administration. 10mg R&D grade extract is also available for clinical trials requiring a second dose format for study.

## Stability

The product has maintained its original potency level without any degradation during stability testing of nine months.

#### Validation

Third-party COA confirms critical information regarding potency, water content, microbial content, and heavy metal content, and confirms that the product meets specific quality specifications.

## Quality

Product development is in accordance with guidelines established by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the requirements of Good Manufacturing Practice (GMP).

## Scalability

Largest genetic bank of Psilocybin in the world. Storage capacity of 2,000kg on site.

"Australian psychiatrists can now prescribe Optimi's MDMA and Psilocybin capsules for therapeutic use in patients. To have both of these GMP drugs in market is a very humbling achievement"

- JJ WILSON

CO-FOUNDER & CHAIRMAN, OPTIMI HEALTH

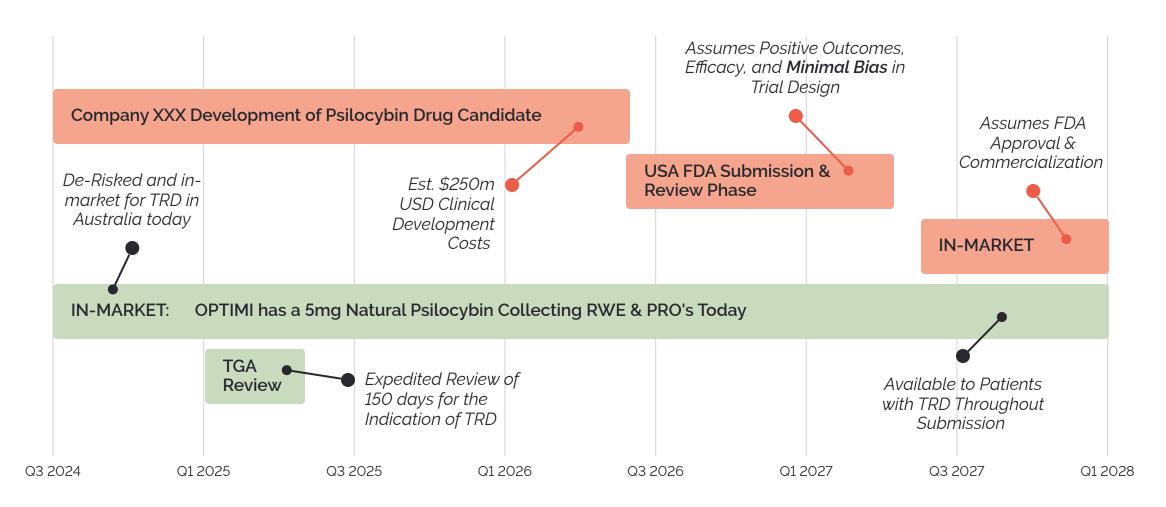
# Market Capitalization & Drug Pipeline Comparison

Comparison of psychedelic company market caps and current drugs in-market as of August 2024 (CAD)

		Optimi	Lykos	Atai	Mind Med	Compass	Cybin
1	Market Capitalization	\$30,000,000	\$400m	\$300m	\$680m	\$650m	\$260m
•	MDMA in Market	•	?	*	*	*	*
7	Psilocybin in Market	<b>✓</b>	*	*	*	*	*
A	In-House GMP Manufacturing	*	*	*	*	*	*
	Drug Establishment Licence	*	*	*	*	*	*

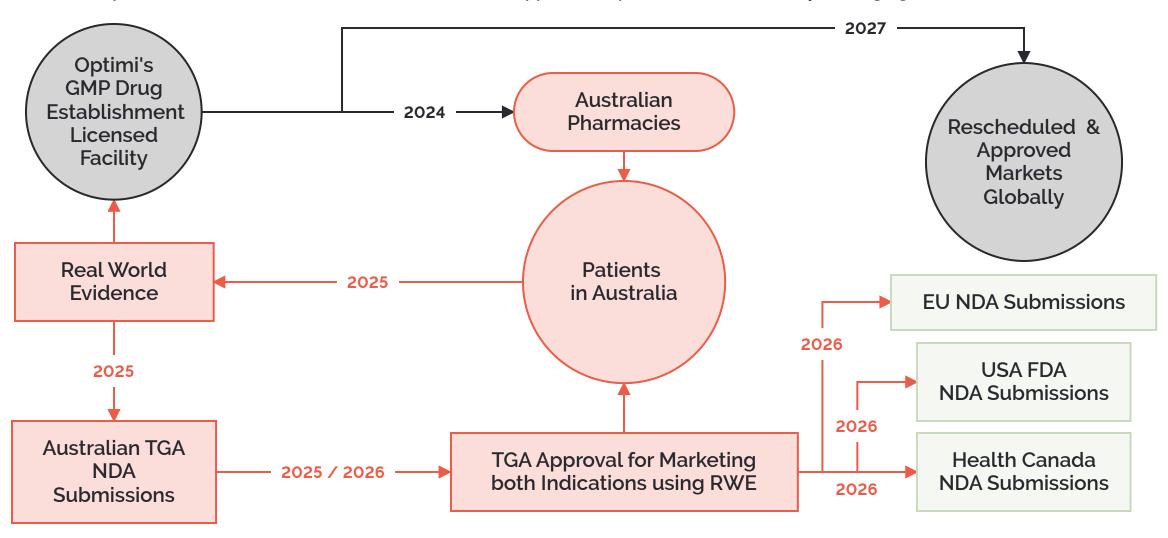
## Psilocybin NDA Pathway for Treatment Resistant Depression

Comparison: Company XXX is hundreds of millions of dollars and years away from being in-market, Optimi is in-market now for TRD.



# Optimi's NDA Pathway for Treatment of PTSD & TRD

With the drug establishment licence, Optimi is authorized by Health Canada to supply MDMA & Psilocybin capsules to Patients in regulated markets. Optimi will collect Real World Evidence (RWE) to support multiple NDA submissions by leveraging real Patient Outcomes (PROs).



## How is Optimi Positioned to Win the Rollout of MDMA & Psilocybin?

5% of the world is depressed... Optimi is ready to deliver cost effective, GMP MDMA & Psilocybin Capsules under their Drug Establishment Licence to regulated markets around the world upon rescheduling.



#### **Cost-Effective Production**

Optimi can produce GMP MDMA &
Psilocybin capsules at a low cost and at
scale to ensure their drugs are the most
competitively priced in the global
marketplace. All large capital
expenditures required are now complete.



### GMP Compliant & Ready to Ship

MDMA 40mg & 60mg and 5mg Natural Psilocybin Extract GMP Capsules are ready to be shipped on demand to any licensed entity able to accept controlled substances through Optimi's GMP compliant Drug Establishment License.



#### **Future Rescheduled Markets**

The Rescheduling of MDMA, Psilocybin, or any other psychedelic compound presents a unique opportunity for Optimi to gain market share immediately while the competition is still in time consuming clinical development phase.

# Pathway to US Exchange Listing in 2026:

As a Health Canada licensed GMP pharmaceutical drug manufacturer, Optimi's MDMA and Psilocybin capsules available by prescription in Australia. The Company is in discussions with US based institutions who have financed US exchange listed psychedelic companies. The majority of Companies are still developing their drugs in clinical trials, and all will require FDA approval before getting their drugs to market. Optimi is significantly de-risked by comparison.



#### Q1 2025

Prepare & submit US Exchange up-listing application, and US bank commitment



#### Q2 2025

Provide required financial and operational documentation for exchange review



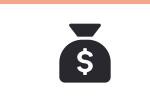
#### Q4 2025

Satisfy exchange minimum listing requirements including market capitalization, share price, and number of shareholders



#### Q1 2026

Receive conditional approval from Nasdaq to list common shares



#### Q2 2026

Complete all prelisting requirements, capital raise, and receive approval for Nasdaq listing



#### Q4 2026

Commence trading on the Nasdaq exchange

# **Executive & Management Team**



Bill Ciprick CEO



Bryan Safarik COO



Jacob Safarik CFO



Dr. Preston Chase CSO



Dane Stevens



Leah Hodges Corporate Secretary



Karina Lahnakoski Director of Quality

## **Board of Directors**



JJ Wilson Chairman & Co-Founder Independent Director



Bryan Safarik
COO & Co-Founder
Director



Jacob Safarik
CFO & Co-Founder
Director



Dane Stevens
CMO & Co-Founder
Director



Jon Schintler
Independant Director

# **Advisory Board**



Chip Wilson



Edward Safarik



Harley Pasternak



Azim Jamal

## **RECENT MEDIA & PRESS**

























# Why Invest in Optimi Now?



Two Psychedelic Drugs Available in a Prescription Market



Access to Real World Data & Patient Outcomes Using Optimi's Products



Strong Financial Support and Backing From Insiders & Founders



Licensed & Ready to Export MDMA & Psilocybin Capsules Globally



Cost-Effective On-Site GMP Manufacturing and Production



Ability to Participate in Future Regulated Markets Imminently

Optimi Health Corp. CSE: OPTI - OTCQX: OPTHF - FSE: 8BN

# **Key Milestones Explained:**

### Optimi's MDMA & Psilocybin Now Prescribable

Australia's Therapeutic Goods Administration has authorized the import of Optimi's MDMA 40mg & 60mg Capsules, and 5mg Natural Psilocybin Extract for the treatment of PTSD, and Treatment Resistant Depression. This means that both of Optimi's drugs are available on a prescription basis to Authorized Physicians in Australia to use in conjunction with therapy.

# Real World Evidence Collection & Patient Outcomes

In partnership with Mind Medicine Australia, Optimi will have access to relevant patient outcomes and evidence pertaining to the use of their MDMA & Psilocybin as a treatment for PTSD and TRD. This data will allow Optimi to collect relevant information for global NDA submissions using real Patient Outcomes for both indications.

## Drug Establishment Licence & GMP Manufacturing

Optimi Health is officially a Health Canada GMP compliant psychedelic drug manufacturer. With the DEL in hand, MDMA & Psilocybin capsules produced at Optimi's facility are available for prescription use in patients where regulation around therapeutic use has occured. This is in addition to the Company's previously issued Controlled Substances & Narcotics Licence.

## Phase II Clinical Trial Partnership for MDD

Optimi's 5mg Natural Psilocybin Extract Capsule is set to be used in a Phase 2 clinical trial for Major Depressive Disorder. This trial will further validate Optimi's drug development initiative for Psilocybin as a safe and viable treatment for Depression, and put Optimi's drug candidate on a pathway for a pre-approved Phase 3 trial in 2025. It is possible that Optimi and Atma receive breakthrough status once phase 2 is complete.



Thank you.

