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(ASX:EMD)

A ***clinical stage*** biotech, informed by the ***patient experience***, tackling unmet needs in ***mental health*** and ***neuroscience***

March 2023

Broker Briefing

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Presentation release authorised by Michael Winlo, CEO and Managing Director

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Advancing CBD & MDMA to address unmet needs in Mental Health & CNS

(EMD : ASX)

[1] ***Tenmile*** = *Forrest Family Health-Focused Investment Fund*

CLINICAL FOCUS

Mental Health & Neuroscience

COMPARATIVE ADVANTAGES

- **Strong register - Tenmile[1] 7.8% / Directors 27% / Top 50 70+%**
- **Unique Ultra-Pure CBD formulations** - delivers clinical advantages
- **Novel MDMA-inspired chemical entities** - substantial preclinical assets
- **Proprietary Real-World Data** - guiding clinical development
- **Front-line clinical delivery *(Emerald Clinics)*** - provides patient access
- **Global leadership team & partners** with drug registration successes

LEADING PROGRAMS & TRACTION

ULTRA-PURE (lab-made) CANNABINOID MEDICINES

- *First dose form (EMD-RX5) in **Phase 3 clinical trials** (ACTRN: 12622001319763)*
- Proprietary "RX" formulation **high bioavailability**, safe, tolerable, **low cost**
- Multiple global drug registration opportunities; **FDA-compliant** formulations

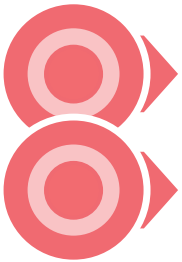
MDMA-INSPIRED MEDICINES (TGA now accepts MDMA as Schedule 8 medicine)

- One of **world's largest MDMA analogue libraries**
- Partnership with University of Western Australia
- Establishing **MDMA-assisted therapy network** in Australia via specialists

IP & PROTECTION

Growing patent library covering **novel formulations**, **methods of treatment** and **new chemical entities**

emyria'S MAJOR DISEASE TARGETS



MILD SYMPTOMS ANXIETY DISORDERS

Problem Size

15% of all adults from time to time

(DOI: 10.25816/5ps1-j259 2021)

>300M w GAD (most prevalent mental health disorder, **& rising**)

(https://ourworldindata.org/mental-health 2021)

Unmet Needs

No over the counter treatments

80% of patients on prescription treatments have at least 1 **side effect**

(Sienaert P., et al 2014)

The Opportunity

CBD shown to be effective in Real-World studies but current products limited by *low purity & potency and high costs*

(Vickery A., et al 2022)

Emyria's Advanced Treatment Programs

Ultra-Pure *"Over the counter"* CBD (slide 11)

Ultra-Pure *"Prescription"* CBD (slide 12)

POST-TRAUMATIC STRESS DISORDER

350M worldwide (>$200B in costs)

(Davis, L. L., et al. 2022)

Up to **50%** of patients **resistant to current treatments**

(ncbi.nlm.nih.gov/books/NBK224874/)

MDMA-assisted therapy showing promising outcomes but delivery challenging

(Mitchell J.M., et al 2021)

MDMA-assisted therapy network (slide 17)

"Faster-acting" MDMA (slide 19)

L-DOPA INDUCED DYSKINESIA ('LID')

10M w Parkinson's (up to **80%** develop **LID** which increases treatment costs **40%**)

(Thanvi B., et al 2007)

Most effective current treatment achieves only **24%** **reduction in symptoms**

(Kwon, D.K., et al 2022)

Case studies have shown **MDMA** can help with symptoms but has unwanted side effects

(http://news.bbc.co.uk/2/hi/health/1169980.stm)

MDMA without the "high" (slide 20)

emyria BUSINESS STRUCTURE & ASSETS

PERSONALISED CARE
+ SERVICE REVENUES

DATA

ADVANCED TREATMENTS
+ COMMERCIAL DEALS

emerald clinics

Specialist cannabinoid clinics caring for 1,000's of Australians - demand is strong

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PaxCentre

A psychiatry network delivering psychedelic-assisted therapy [1]

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REAL-WORLD DATA

Dose responses, clinical outcomes, product intelligence

Supports development of new treatments

ULTRA-PURE CBD

EMD-RX5 (over-the-counter CBD)
IN PHASE 3

EMD-RX7 (prescription)
PREPARING FOR PHASE 1

MDMA-INSPIRED THERAPIES

MDMA-ASSISTED THERAPY MODEL
Licenced care model & MDMA package

MDMA ANALOGUES
Next-gen MDMA tackling neuropsychiatric disorders

SOURCE: 1. See ASX Release 07 Mar 2023

“DELIVERY & DATA” DE-RISKS & ***ACCELERATES*** DRUG REGISTRATION

TRADITIONAL DRUG DEVELOPMENT (costly, time-intensive, high-risk) →

emyria **DRUG DEVELOPMENT APPROACH** (Gather insights with patients to de-risk & accelerate drug development) → *time*

Real-World Data Informs indication selection and trial design

Ultra-Pure CBD → RX7 → RX5

MDMA analogues

LEADERSHIP | GLOBAL DRUG DEVELOPMENT & COMMERCIALISATION SUCCESSES

Dr Stewart Washer
Executive Chairman
PhD (Microbiology)

- Emyria founder, largest shareholder
- Founded multiple ASX companies
- Multiple trade sales

Prof Sir John Tooke
Non-Executive Director &
Chair of the Risk Committee
FRCP, FMedSci

- Knighted for services to medicine
- Clinician researcher - past President AMS
- Advisor to NHS on “learning health systems”

Dr Karen Smith
Executive Director
MD, PhD, MBA, LLM

- Experienced biopharma C-suite exec
- Overseen 20+ FDA approvals
- Multiple, $B+ M&A completions

Dr Michael Winlo
CEO & Managing Director
MBBS(Hons), MBA (Stanford)

- Data, trials and drug development
- Paper-to-digital at Linear
- Founding five, Palantir Health Team

C/Prof Alistair Vickery
Medical Director
MBBS, FRACGP, FCHSM

- Big Data researcher, epidemiology
- Chair of Black Swan Health
- Professor of Medicine at UWA

Matt Callahan
Non-Executive Director
LLB

- 4 FDA approvals
- Venture capital experience
- Successful exit - iCeutica to Iroko

MARKET OPPORTUNITY FOR **CANNABINOIDS**

A single registered product sells

> $1B/year [1]

$2B spent on clinical development [2]

Acquired by Jazz for **US$7.2B** [3]

FDA-approved as small molecule *(still plant-based)* [4]

Limited to rare disease indications [5]

Oil dose form with limited GI tolerability [5]

BUT, TODAYS CBD

PRODUCTS

Variable potency [6]
(inaccurate labels)

Impurities present
(most plant-base with THC & heavy metals)

Poor bioavailability [5]
(only 6.5% average)

Expensive [7]
($200-800/m low dose)

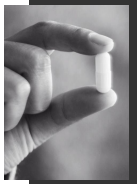
Limited dose forms
(most are oils)

emyria FORMULATIONS

Proprietary, solid, oral CBD

Registration for **multiple indications**

OTC & **prescription**.



Ultra-Pure CBD
lab-made, *no THC* or *impurities*

FDA Drug Master File (API)
facilitates FDA approval

Excellent Bioavailability,
less dose variability, lower costs, lower environmental impact

SOURCES:
1. https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-full-year-and-fourth-quarter-2022
2. https://www.europeanpharmaceuticalreview.com/news/152570/highest-british-business-award-goes-to-cannabis-drug-developer-gw-pharmaceuticals/
3. https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-completes-acquisition-of-gw-pharmaceuticals-plc-301284512.html
4. GW Pharmaceuticals Annual Report June 2018
5. https://www.tga.gov.au/sites/default/files/auspar-cannabidiol-210115.pdf
6. Johnson, E., Kilgore, M. & Babalonis, S. Label accuracy of unregulated cannabidiol (CBD) products: measured concentration vs. label claim. J Cannabis Res 4, 28 (2022). https://doi.org/10.1186/s42238-022-00140-1
7. https://freshleafanalytics.com.au/wp-content/uploads/2021/10/FreshLeaf-Analytics-H2-2021.pdf

ANXIETY DISORDERS

Excessive, persistent fear and excessive worry that interferes with daily activities.

3.9% *of all adults - most common mental health concern, globally.* [1]

Up to 80% patients *experience at least one side effect from common prescription treatments* [2]

CANNABINOID THERAPY

PUBLISHED EVIDENCE:
"The most replicable results...related to the ability of ***CBD...to ameliorate anxiety****".* [3]

EMYRIA'S REAL-WORLD DATA:
Long-term data on ~4,000 patients reveals ***improvements in anxiety*** *& stress as measured on DASS-21* [4]

BUT most CBD products

- *Plant-based oils*
- *Low purity*
- *Low bioavailability*
- *High cost*

THEREFORE:

- *No registered OTC product*
- *No prescription dose form for anxiety*

emyria OPPORTUNITIES

OVER-THE-COUNTER CBD (EMD-RX5)

- FDA-compliant / global potential
- **In Phase 3 trials** pursuing TGA "over-the-counter" registration for mild **anxiety/stress** (~15% of pop.)
- Low cost of goods

PRESCRIPTION CBD (EMD-RX7)

- **Potent** dose form, **high bioavailability**
- **Multiple indication** potential
- **Preparing for Phase 1 trials**

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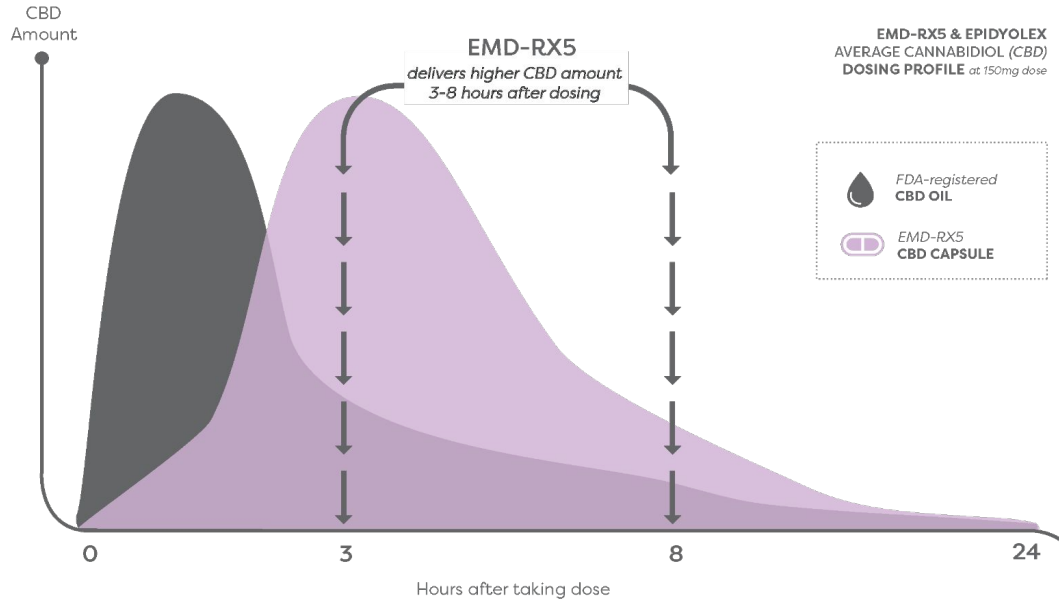
SOURCES:
1. https://ourworldindata.org/mental-health#anxiety-disorders
2. Sienaert, Pascal. "Managing the adverse effects of antidepressants." Psychiatric Times, vol. 31, no. 7, July 2014
3. Arnold, JC, McCartney, D, Suraev, A, McGregor, IS. The safety and efficacy of low oral doses of cannabidiol: An evaluation of the evidence. Clin Transl Sci. 2023
4. Vickery, AW, Roth S, Ernenwein T, Kennedy, J, Washer, P,. A large Australian longitudinal cohort registry demonstrates sustained safety and efficacy of oral medicinal cannabis for at least two years medRxiv 2022.07.22.22277770

EMD-RX5 | ULTRA-PURE CBD *CAPSULE* **VS** EPIDYOLEX™ *OIL IN PHASE 3 CLINICAL TRIALS* *(due to complete H2, 2023)*

In head-to-head with **Epidyolex: EMD-RX5** was safe & well tolerated with:
(1) high bioavailability (2) slow release profile (3) lower dose variability



EMD-RX5 currently pursuing TGA registration:

In active Phase 3 clinical trials
due to complete H2, 2023

Ultra Pure CBD with a Drug Master File (DMF)
allows assessment as "small molecule" with FDA after TGA registration

Suitable for multiple registration opportunities
Ready for indication, and geographic, expansion

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SOURCES:
1. See ASX release 25 May 2022

EMD-RX5 | GLOBAL OVER-THE-COUNTER OPPORTUNITY

2.8M
Adults with Chronic Pain

INITIAL INDICATION

Of these, **1.4M** have symptoms of anxiety or stress [1]

Indication expansions

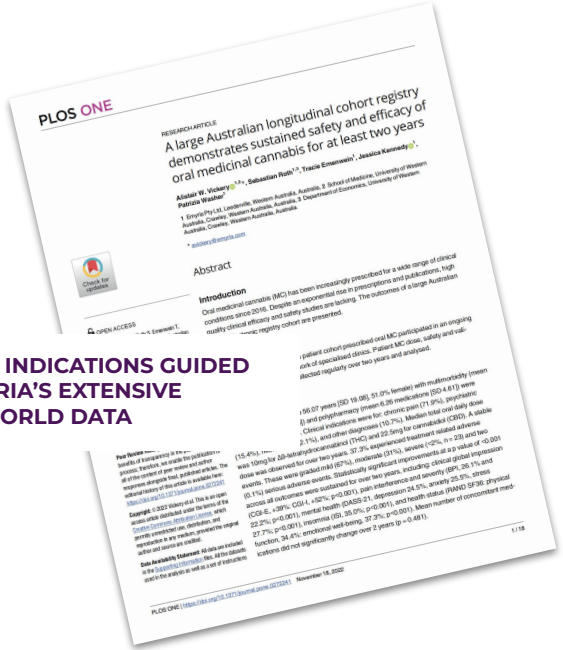
IRRITABLE BOWEL SYNDROME

15% of population [3]
High prevalence of
anxiety symptoms [4]

Market expansions

The symptoms of **psychological distress** affect **~15%** of all adults [2]

FUTURE INDICATIONS GUIDED BY EMYRIA'S EXTENSIVE REAL-WORLD DATA



PLOS ONE

RESEARCH ARTICLE

A large Australian longitudinal cohort registry demonstrates sustained safety and efficacy of oral medicinal cannabis for at least two years

Alistair W. Vickery, Patricia Wallace

Abstract

Introduction

Oral medicinal cannabis (MC) has been increasingly prescribed for a wide range of clinical conditions since 2016. Despite an exponential rise in prescriptions and publications, high quality clinical efficacy and safety studies are lacking. The outcomes of a large Australian

PLOS ONE | https://doi.org/10.1371/journal.pone.0272041 November 18, 2022 1 / 18

SOURCES:
1. Hnatešen D, Pavić R, Radoš I, Dimitrijević I, Budrovac D, Čebohin M, Gusar I. Quality of Life and Mental Distress in Patients with Chronic Low Back Pain: A Cross-Sectional Study. Int J Environ Res Public Health. 2022 Aug 26;19(17):10657.
2. Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221.
3. https://gi.org/topics/irritable-bowel-syndrome/
4. Banerjee A, Sarkhel S, Sarkar R, Dhali GK. Anxiety and Depression in Irritable Bowel Syndrome. Indian J Psychol Med. 2017 Nov-Dec;39(6):741-745

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EMD-RX7 | HIGHLY BIOAVAILABLE **ULTRA-PURE CBD** FOR PRESCRIPTION USE

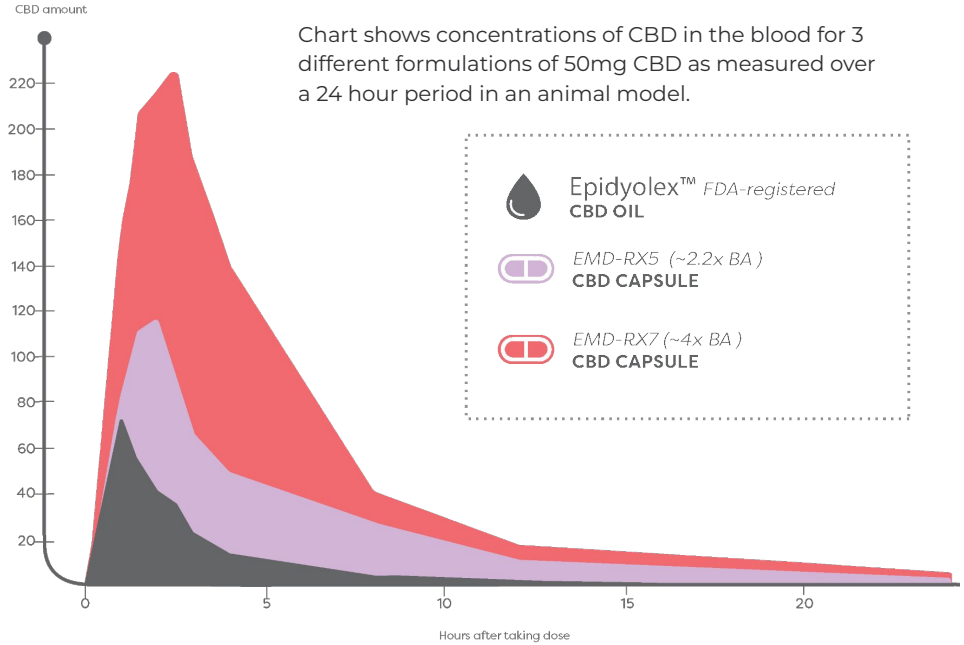

Chart shows concentrations of CBD in the blood for 3 different formulations of 50mg CBD as measured over a 24 hour period in an animal model.

Epidyolex™ *FDA-registered*
CBD OIL

EMD-RX5 (~2.2x BA)
CBD CAPSULE

EMD-RX7 (~4x BA)
CBD CAPSULE

EMD-RX7 showed **more than 4 times the bioavailability** of Epidyolex [1]

Phase 1 trials and advanced preclinical screening in planning alongside the selection of FDA-focussed indications via 505(b)2 pathway. [2]

KEY INSIGHT **HIGHER BIOAVAILABILITY CBD** has potential to support multiple, global prescription registrations

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SOURCES:
1. See ASX announcement 17 March 2022
2. See ASX announcement 28 November 2022

WHAT'S NEXT? | ADVANCED CANNABINOID DEVELOPMENT

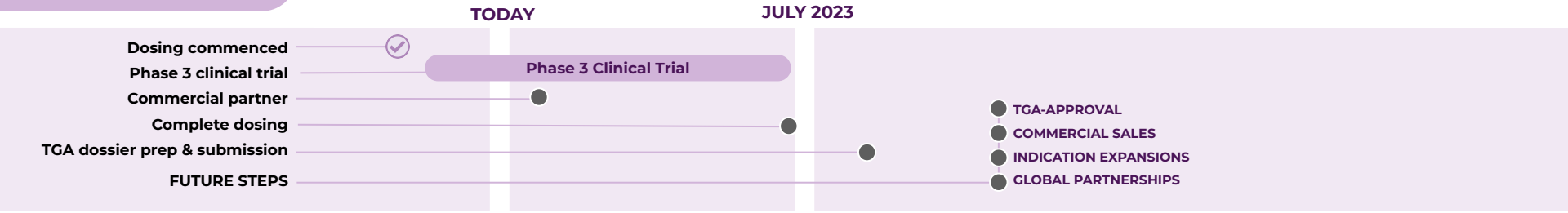
DRUG DEVELOPMENT

Completed Next Steps

H1 2023 | H2 2023

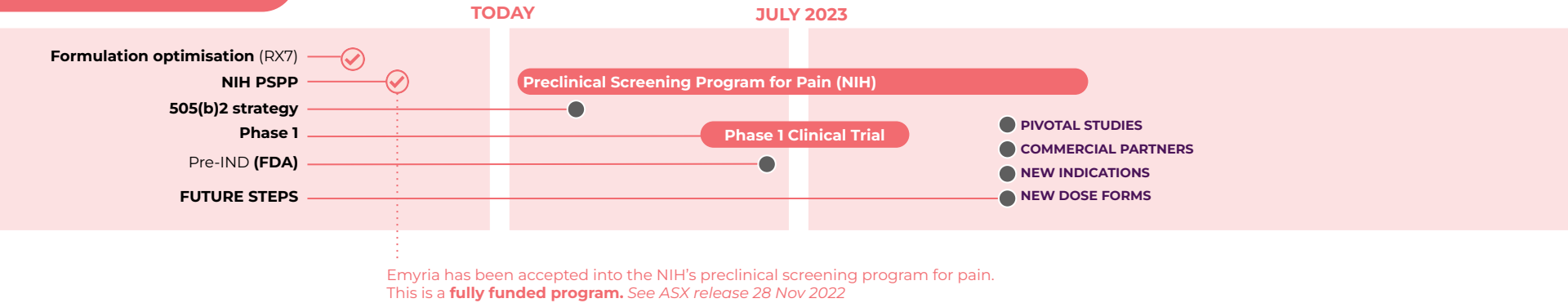
EMD-RX5
OVER THE COUNTER

Complete pivotal Phase 3 clinical trial for **EMD-RX5** to support **TGA registration**



EMD-RX7
PRESCRIPTION

Complete preclinical screening & Phase 1 trial of **EMD-RX7** to support prescription opportunities

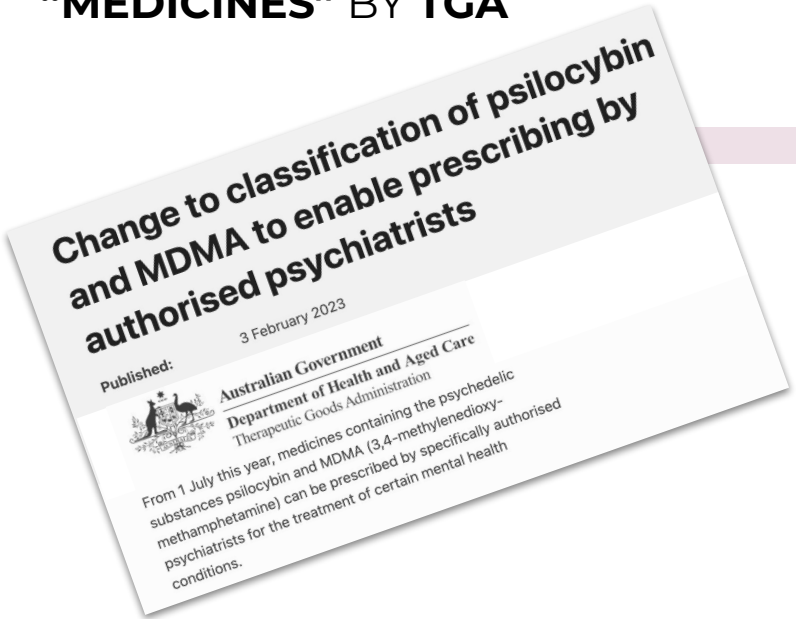


Emyria has been accepted into the NIH's preclinical screening program for pain.
This is a **fully funded program.** *See ASX release 28 Nov 2022*

MDMA & PSILOCYBIN RECOGNISED AS **“MEDICINES”** BY **TGA**

HOWEVER…

*ONLY AVAILABLE VIA **PSYCHIATRISTS** OR CLINICAL TRIALS*



Change to classification of psilocybin and MDMA to enable prescribing by authorised psychiatrists

Published: 3 February 2023

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

From 1 July this year, medicines containing the psychedelic substances psilocybin and MDMA (3,4-methylenedioxy-methamphetamine) can be prescribed by specifically authorised psychiatrists for the treatment of certain mental health conditions.

*“For approval to prescribe, psychiatrists will need to demonstrate **appropriate training,** patient selection, **evidence-based treatment protocols** and **patient monitoring**.*

*Further, ongoing **psychotherapeutic support remains an essential component** of the psychedelic treatment model.”*

-RANZCP *(College of Psychiatrists)*

The Royal Australian & New Zealand College of Psychiatrists

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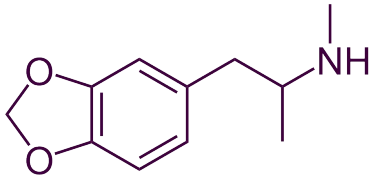
WHAT IS **MDMA**?



MDMA *(3,4-methylenedioxymethamphetamine or "ecstasy")*
- an amphetamine that causes release of 3 neurotransmitters:

1

Serotonin
contributes to *mood, prosocial effects*

2

Dopamine
associated with *reward, euphoria*

3

Noradrenaline
stimulant activity, attention

MDMA is the best known member of the **"entactogens"** - drugs that produce feelings of ***emotional communion*****,** oneness, relatedness, emotional openness and fear extinction.

UNIQUE PSYCHOPHARMACOLOGICAL **EFFECTS OF MDMA**

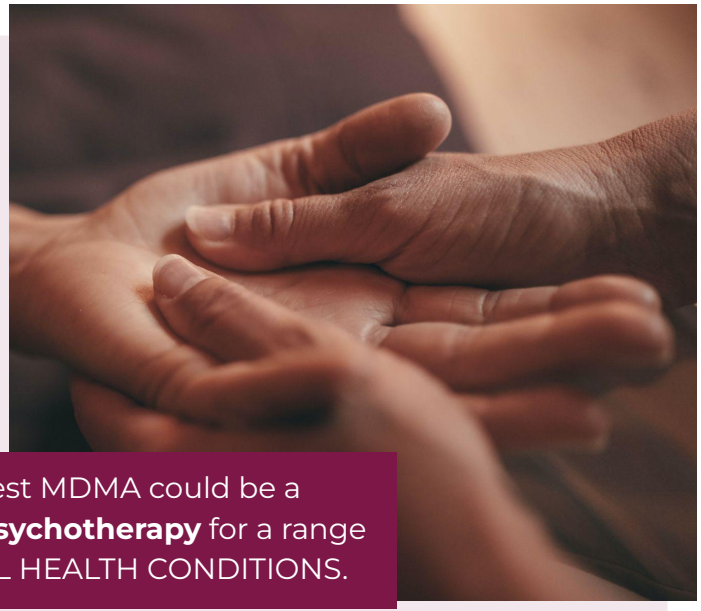
INCREASED

- feelings of wellbeing
- sociability and extroversion
- interpersonal trust

AN ALERT BUT ALTERED STATE OF CONSCIOUSNESS

DECREASED

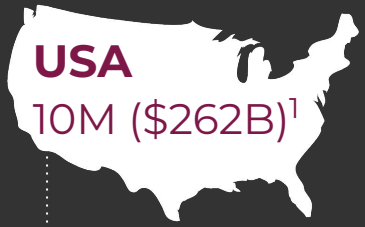
- feelings of fear & defensiveness



These effects suggest MDMA could be a promising **adjunct to psychotherapy** for a range of challenging MENTAL HEALTH CONDITIONS.

POST-TRAUMATIC STRESS DISORDER

A chronic, debilitating mental health disorder that can occur following a traumatic event



TREATMENT OPTIONS FOR PTSD

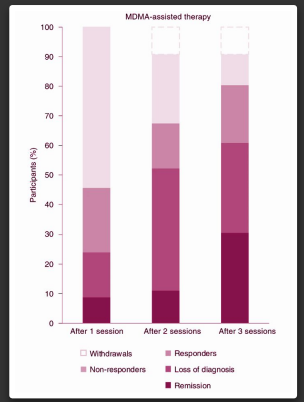
- **COUNSELLING & PSYCHOTHERAPY**
- **PRESCRIPTION**
- **EXPOSURE THERAPY** Re-imagining events in a safe environment
- **GROUP THERAPY**

Up to 50% treatment resistance [2]

MDMA-ASSISTED THERAPY

Providing of MDMA with therapy.

TGA Schedule 8 Medicine
(from July 1st)



***67% of participants** in the MDMA group **no longer met criteria for PTSD** two months after the sessions. (c/w 32% of participants in the placebo group)* [3]

BUT delivery is complex & costly
- *Requires special training + facilities*
- *Strict drug management*

- **Long Sessions** *(8+ hrs)*
- *Strict patient selection criteria*

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BUILD MDMA-ASSISTED THERAPY NETWORK DELIVERING

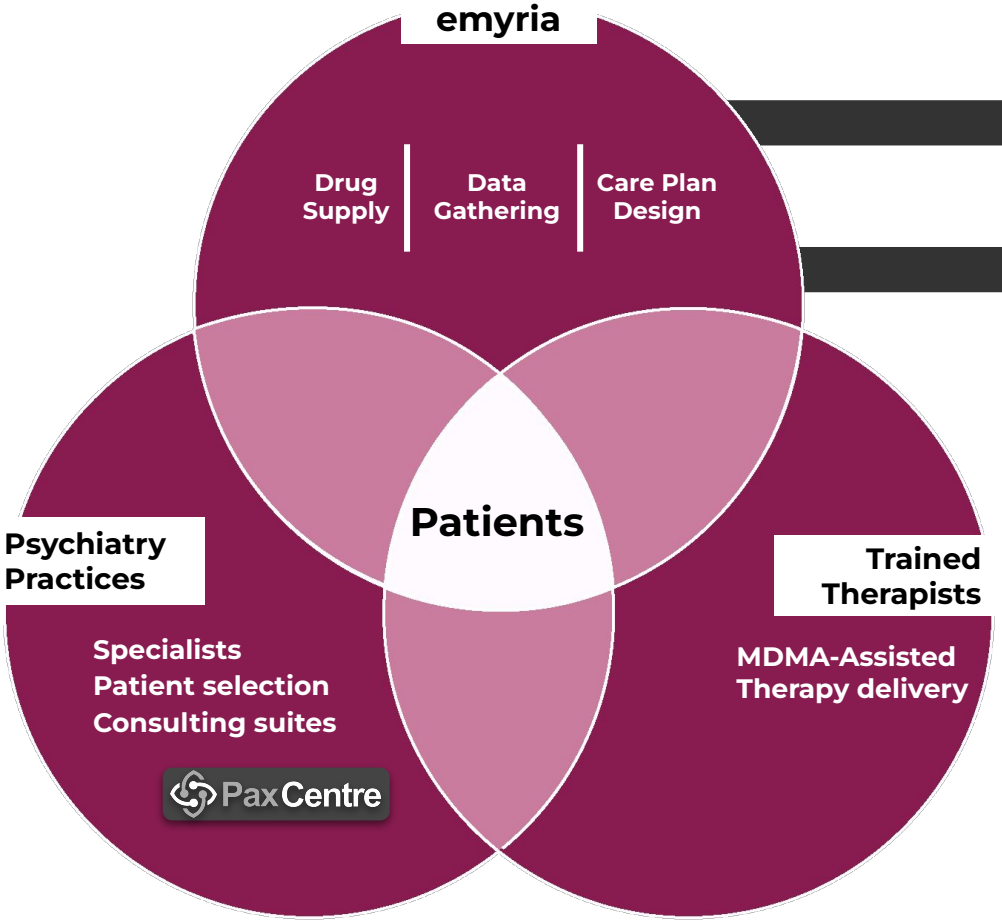
- **Patient outcomes**
- **Licence revenues**
- **Real-World Data**

CREATE "NEXT-GEN" MDMA DELIVERING

- ***Faster onset MDMA***
- **Safer MDMA** *(fewer side effects)*
- **Novel treatments for neuropsychiatric disorders**

SOURCES:
1. Davis LL, Schein J, Cloutier M, et al. The economic burden of posttraumatic stress disorder in the United States from a societal perspective. J Clin Psychiatry. 2022;83(3):21m14116
2. Committee on the Assessment of Ongoing Efforts in the Treatment of Posttraumatic Stress Disorder; Board on the Health of Select Populations; Institute of Medicine. Washington (DC): National Academies Press (US); 2014 Jun 17.
3. Mitchell, J.M., Bogenschutz, M., Lilienstein, A. et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 27, 1025–1033 (2021)

1) BUILDING AN MDMA-ASSISTED THERAPY NETWORK



Revenues

Real-World Data

- Cost-effectiveness analysis
- Care model improvement

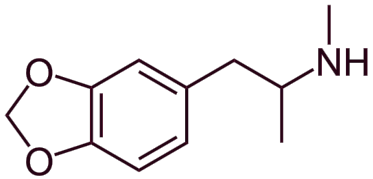
&

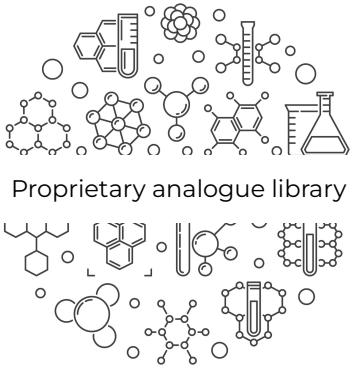
- **Novel drug development**

2) CREATING "NEXT-GEN" MDMA

with THE UNIVERSITY OF WESTERN AUSTRALIA

Take MDMA as inspiration → **Design & synthesise new analogues** → **Advanced screening** → **Prioritise indications**





>140 novel chemical entities and growing

- Pharmacology (target) screens
- Safety screens
- Behavioural studies
- Metabolism assays
- Peripheral effects

PTSD
(Faster MDMA)

L-DOPA Induced Dyskinesia
(MDMA "without the high")

Non-neurological
(eg. Fibrotic diseases)

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ANALOGUE DEVELOPMENT GOAL

FASTER-ACTING MDMA

WHY? MDMA-assisted therapy has potential to address PTSD.

BUT → Therapy sessions can last 6-12 hours. *This limits the number of patients that can be treated per day per site.*

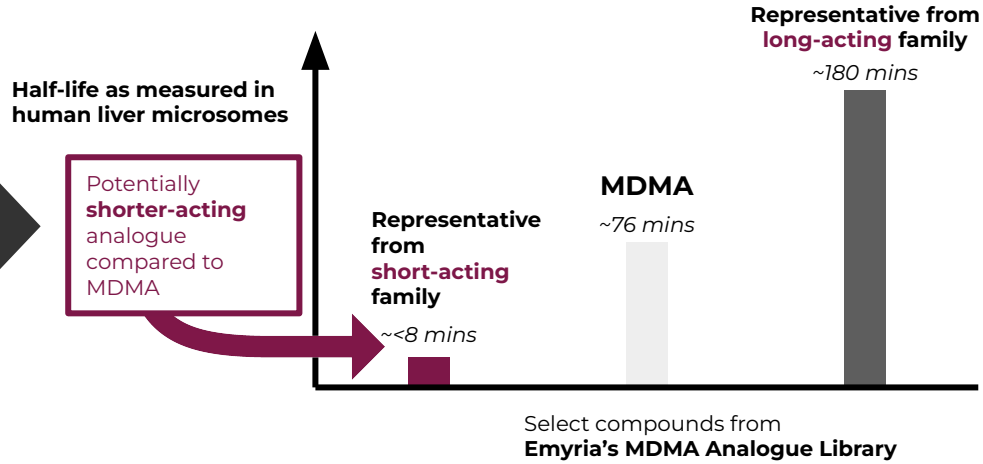
GOAL: *Faster-acting MDMA could shorten treatment sessions and allow more patients to be treated per site*

COMMERCIAL: New chemical entities have strong strong IP and license potential.

Shortening treatment session times could ***increase number of patients that can be treated per site.***

EARLY RESULTS:

Metabolic studies performed to-date demonstrate Emyria's compound library contains novel MDMA analogues with both **rapid-**, and **long-acting** metabolism profiles.



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SOURCE:
1. See ASX Release 12 Oct 2022

ANALOGUE DEVELOPMENT GOAL

MDMA WITHOUT THE "HIGH"

WHY? MDMA improves symptoms of ***"L-DOPA induced dyskinesia"***. [1] A common side-effect of Parkinson's treatment.

BUT → MDMA has unwanted side-effects *(euphoria, increased sociability, amphetamine effects)*

GOAL: *An "MDMA-like" drug that delivers antiparkinsonian benefits* ***"without the high"***

COMMERCIAL: Drugs with antiparkinsonian benefits can generate strong commercial returns:

Example:

- Ongentys™ (*opicapone*) increases "ON-time" by ~6% over 24 hours [2]
- Expected peak sales of US$300M/year [3]

DAY 1 L-DOPA **+** placebo

DAY 2 L-DOPA **+** ecstasy

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SOURCE:
1. See ASX Release 01 Sep 2021
Video - BBC documentary "Agony and Esctasy"

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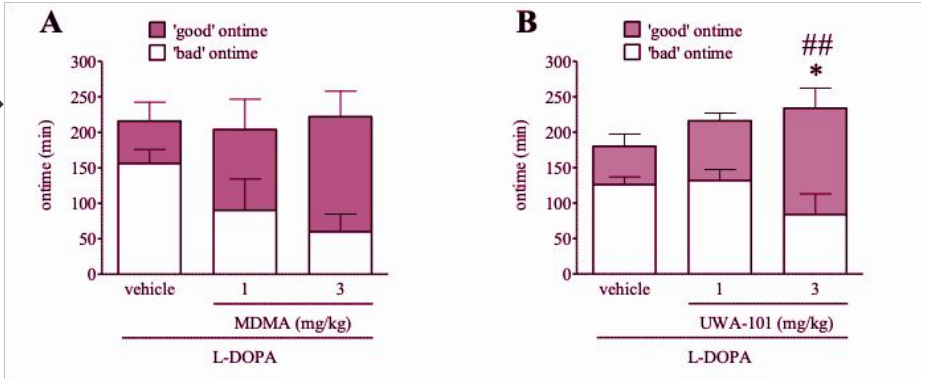
EARLY RESULTS (UWA-101):

In gold-standard preclinical model:

Increased the total duration of L-DOPA-induced **antiparkinsonian benefit** (total ON-time) **by ~30%**.

Significantly increased the **duration of "good" quality ON-time by 178%.** [4]

Additional novel compounds are in preclinical screening.



SOURCE:
1. See ASX Release 01 Sep 2021

MDMA-INSPIRED DRUG DISCOVERY | MULTIPLE **$B** OPPORTUNITIES

Clinical focus	Role of MDMA?	Goals for analogue program	Early proof-of-concept?	What's next?
***Treatment Resistant* PTSD** (5% adults, 30-50% treatment resistant) **Costs of $25B/year** [1]	MDMA increases feelings of *compassion* and *sociability* while reducing *fear* & *defensiveness*. Phase 3 trials have shown MDMA-assisted therapy can have a profound benefit.	**Faster-acting MDMA** with improved tolerability could increase the potential pool of patients.	Sub-set of analogues show faster rates of metabolism.	Advanced screening to identify rapidly metabolised compounds.
***L-DOPA induced dyskinesia* in Parkinson's Disease** (40% of PD patients at 4 years of treatment) **Costs of $1B/year** [2]	MDMA has been shown to improve the "on-time' (beneficial effects) of L-DOPA but has numerous, unwanted side-effects.	**Remove the "high" from MDMA** while preserving beneficial effects on movement disorders.	Gold-standard preclinical model demonstrates analogues can increase on-time by 200%. C/W recently approved PBS drug (Ongentys) which increases on-time by 1hr/24hrs.	Advance new compounds. Long-term safety and tolerability studies.
Fibrotic disease (1.2M patients globally) **Costs of $3B/year** [3]	Some analogues can induce fibrosis. Can MDMA analogues be developed to *reduce* it?	**Identify compounds with 5HT2B antagonism** (a known target for anti-fibrosis medicines).	Cell assays demonstrate reduced collagen deposition at test concentrations.	Further proof-of-concept studies to identify lead compounds.

SOURCES:
1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7366572/
2. https://www.nature.com/articles/s41531-020-0117-1
3. https://www.lung.org/lung-health-diseases/lung-disease-lookup/pulmonary-fibrosis/patients/how-is-pulmonary-fibrosis-treated

MDMA-INSPIRED DRUG DISCOVERY NEXT 12 MONTHS

with THE UNIVERSITY OF WESTERN AUSTRALIA

- **EXPAND** the MDMA-analogue library
- **DELIVER RESULTS** from preclinical screening
- **FILE ADDITIONAL PATENTS** and pursue commercialisation discussions
- **SELECT LEADS** for further proof-of-concept efficacy studies in animal models

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emyria INVESTMENT **HIGHLIGHTS**

1

Significant target markets

Emyria's treatment programs are targeting major unmet needs in **multiple, $Billion+ markets**:

PTSD

Anxiety disorders

Parkinson's disease

Complex pain

2

Advanced clinical programs

First **Ultra-Pure CBD** dose form in **Phase 3 trials; partnership ready**

US-focused registration programs

MDMA-assisted therapy network in development

3

Favourable regulatory environment

TGA rescheduled **MDMA** & psilocybin *(following similar changes for medicinal cannabis in 2016)*

Opens pathway to **registration** & **reimbursement** for Emyria's novel analogues

4

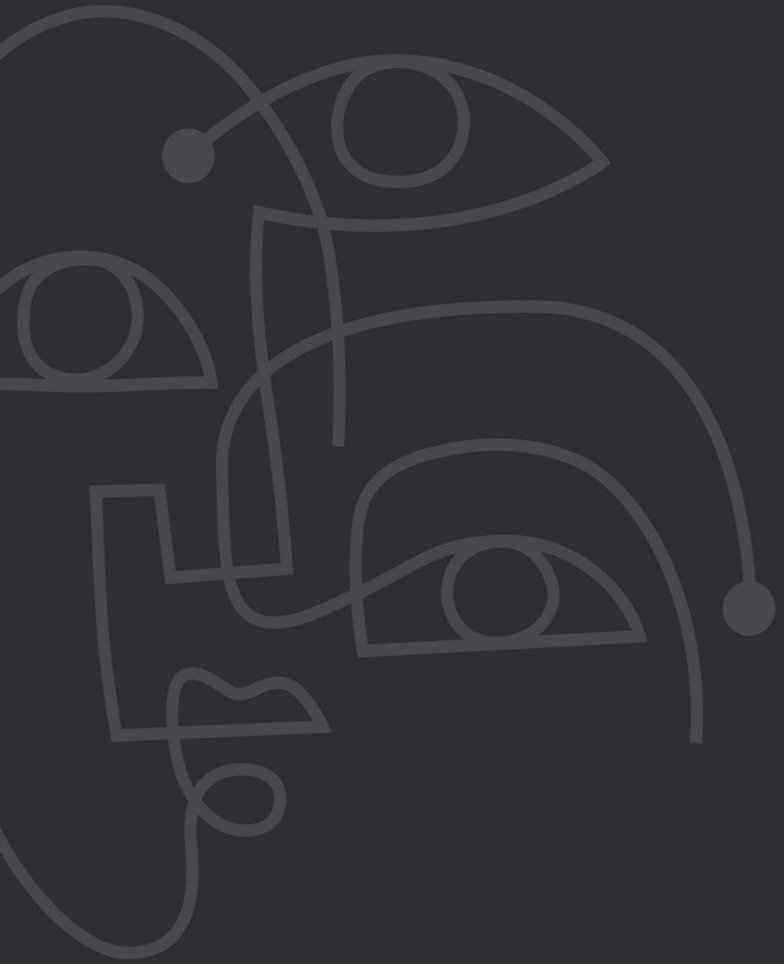
Substantial R&D pipeline

One of world's largest MDMA analogue libraries - novel, neuroactive molecules with potential to become novel neuropsychiatric treatments

5

Advanced capabilities & world-class team

Emyria's in-house expertise has had multiple FDA registrations with deep knowledge of drug development, data analysis & patient care.



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