

# Emyria (ASX:EMD)

*Drug development update*

01 June 2022 | Dr Michael Winlo, MD & CEO

myriad data.  
individual care.

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**Presentation release authorised by Michael Winlo, CEO and Managing Director**

# ACCELERATING DRUG DEVELOPMENT

Traditional drug development (*costly, time-intensive, high-risk*)

time →

Find a *target*,  
generate a *hit*

Create a  
*dose form*

Prove *safety*  
& *efficacy*

Regulatory *approval*

**emyria**



Accelerated with *Real World Data*

Known *targets*,  
and *hits*

Improved &  
unique *dose*  
*forms*

Evaluate *safety*  
& *efficacy* in *real*  
*patients* & *trials*

Regulatory *approval*

# emyria

A biotech that, *uniquely*

develops **treatments**, **backed by data**, **collected with patients** we care for



## TREATMENTS

Proprietary drug design  
and global registration



## DATA

Clinical insights from  
Real-World Data (RWD)



## CARE

New treatments access for  
patients with unmet needs

# Leadership Team - Professionals with **Purpose**



**Global Experience**



**~10 Biotechs**

**20 +**

**FDA approvals**

# BOARD WITH DRUG REGISTRATION & DEEP BIOTECH EXPERIENCE



**Dr Stewart Washer**  
Chairman & Founder



**Matt Callahan**  
Non-Executive Director



**Prof Sir John Tooke**  
Non-Executive Director &  
Chair of the Medical Advisory



**Board**  
**Dr Alistair Vickery**  
Medical Director, Specialist GP



**Dr Karen Smith**  
Executive Director



**Board**  
**Dr Michael Winlo**  
CEO & Managing Director



# CAPITAL STRUCTURE

## KEY METRICS VALUE

Shares on issue 254m

Last close ( 31 May 2022) A\$0.275

**Market Capitalisation (31 May 2022) A\$75.6M**

Cash (31 Mar 2022) A\$6.6m

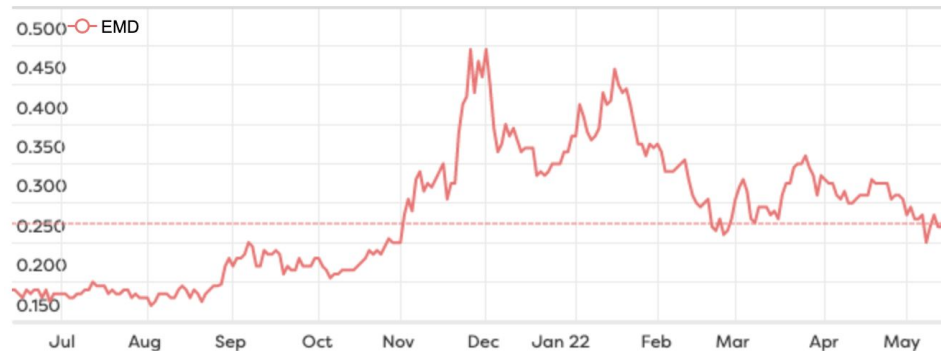
Debt (31 Mar 2022) -

**Enterprise value A~\$69m**

**TOTAL OPTIONS**  
(exercise price \$0.114-0.45)  
*expiring. 2022-24* **62m**



## SHARE PRICE PERFORMANCE





# Emyria's **Treatments**





# PURSUING MULTIPLE, BILLION DOLLAR OPPORTUNITIES

## Proprietary Asset

Real World Data on  
> **6,000 patients**  
with unmet needs



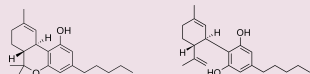
> **100 novel, MDMA**  
analogues  
developed >10 yrs



## Program

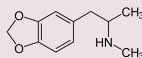
**EMD-RX**  
cannabinoids

**Ultrapure CBMTs for  
multiple indications**



**MDMA**  
analogues

**MDMA-like medicines for  
neurological disorders**



## Status

### Clinical:

- **EMD-RX5:** low-dose CBD for OTC indications
- **EMD-RX7:** high-dose CBD for prescription indications
- **Additional formulations in development**

### Preclinical:

- Expanding library
- Compound screening
- Commencing animal studies
- Filing IP

## Clinical indication & commercial strategy

- One of first to Australian OTC registration (>**US\$200m/yr**) [1]
- Then, on to FDA and other global markets (**US\$1B+**) [2]

- "Next generation" psychedelic-assisted therapies for major mental health disorder e.g. PTSD (**US\$1B+**) [3]
- New neurological disorder treatments e.g. Parkinson's (**US\$1B+**) [4]

# Ultra-Pure CANNABINOID MEDICINES

**Learn what works from  
real patients** (*Real  
World Data*)



**Create reliable treatments**  
(*formulation development*)

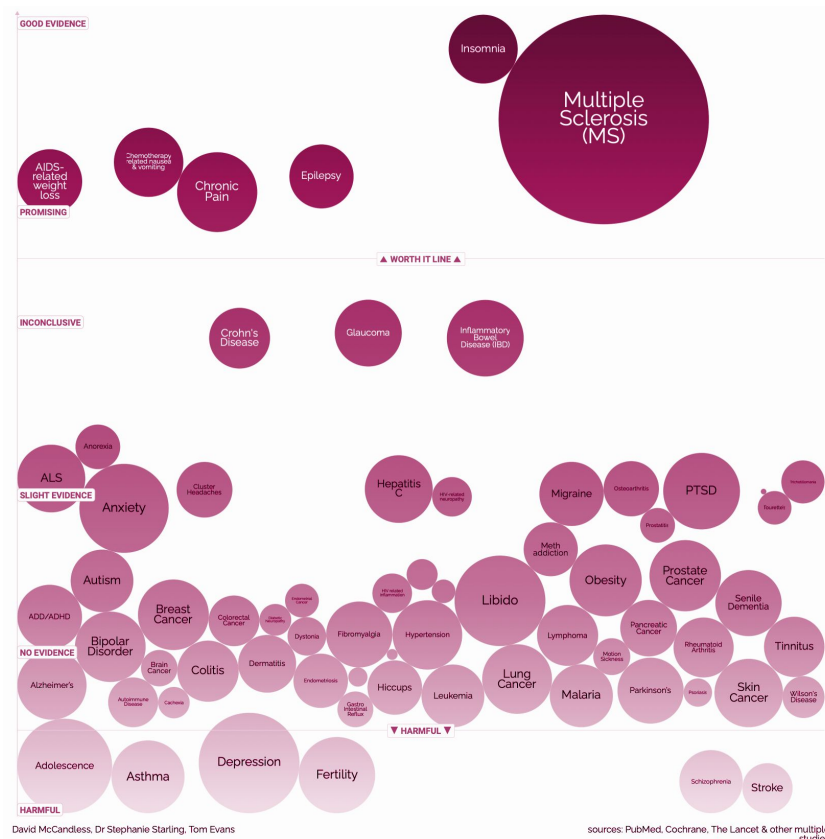


**Pursue  
registration**



PROBLEM 1:

# MEDICINAL CANNABIS LACKS CLINICAL EVIDENCE



# LEARN FROM REAL-WORLD PATIENTS

Emyria has Real-World Data from over

**6,000** Patients  
*(and growing)*

**5** Australian  
Clinical Sites



Emyria is treating more than

**40** Complex  
Conditions

**54%** Patients  
presenting with symptoms of  
moderate to SEVERE ANXIETY



Emyria clinicians have prescribed  
**>50** CBMT products



PROBLEM 2:

# MEDICINAL CANNABIS STUCK AT “2.0”

## MEDICINE

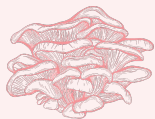
1.0 Natural Origins

2.0 1st Medical Use

3.0 Registered Drug

Patient Impact & Commercialisation

**Statins**  
Lowers Cholesterol



**Pleurotus  
Ostreatus**  
(oyster mushroom)

**1970's**  
First discovered

**1987**  
synthetically developed

**US \$95bn**  
Lipitor Lifetime sales

**Aspirin**  
Relieves minor aches,  
pains, and fevers



**Salix  
Alba**  
(white willow)

**~400 BCE**  
Prepared as a tea

**1899**

**US \$750M**  
2020 revenue "aspirin cardio"

**Cannabis**  
Relieves pain, an  
approved treatment  
for epilepsy



**Cannabis  
Sativa**  
(Cannabis)

**~8000 BCE**  
First medicinal  
use documented

**Emyria's** leading a unique  
pharmaceutical  
formulation program to  
support **multiple medical  
registrations**

**US \$B**  
Multiple, billion dollar  
opportunities in **mental  
health & chronic pain**

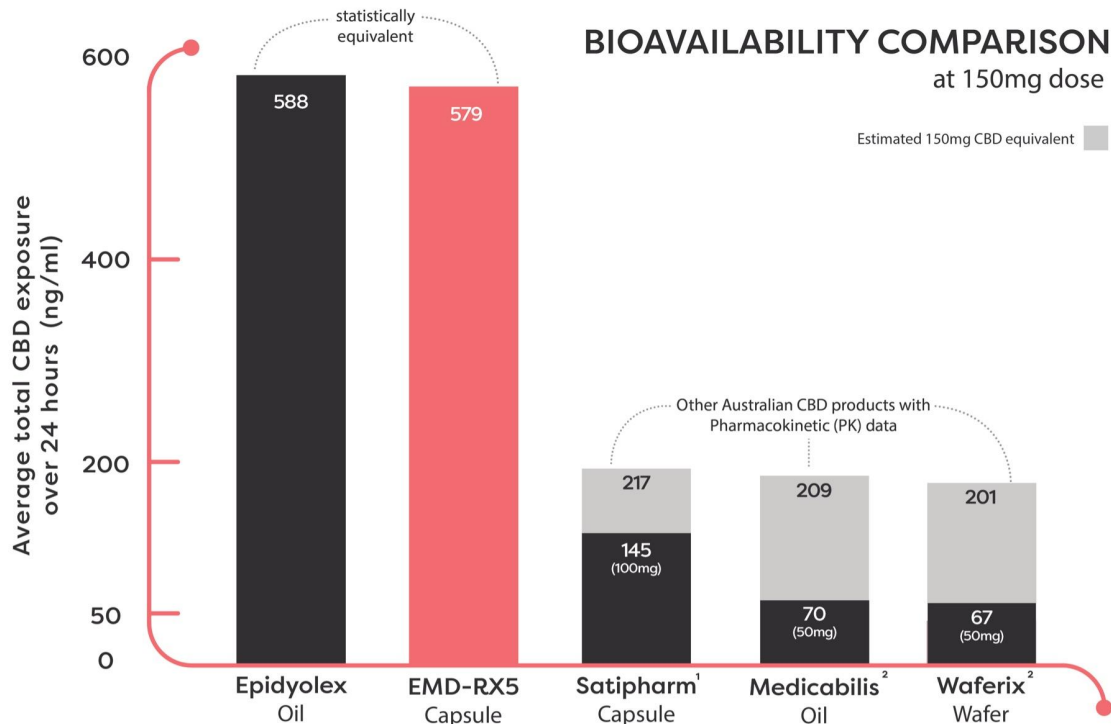
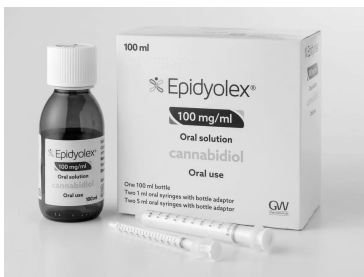
PROBLEM 3:

# CANNABIDIOL (CBD) HAS POOR BIOAVAILABILITY

Oral CBD has weak  
bioavailability  
as low as **6.5%**

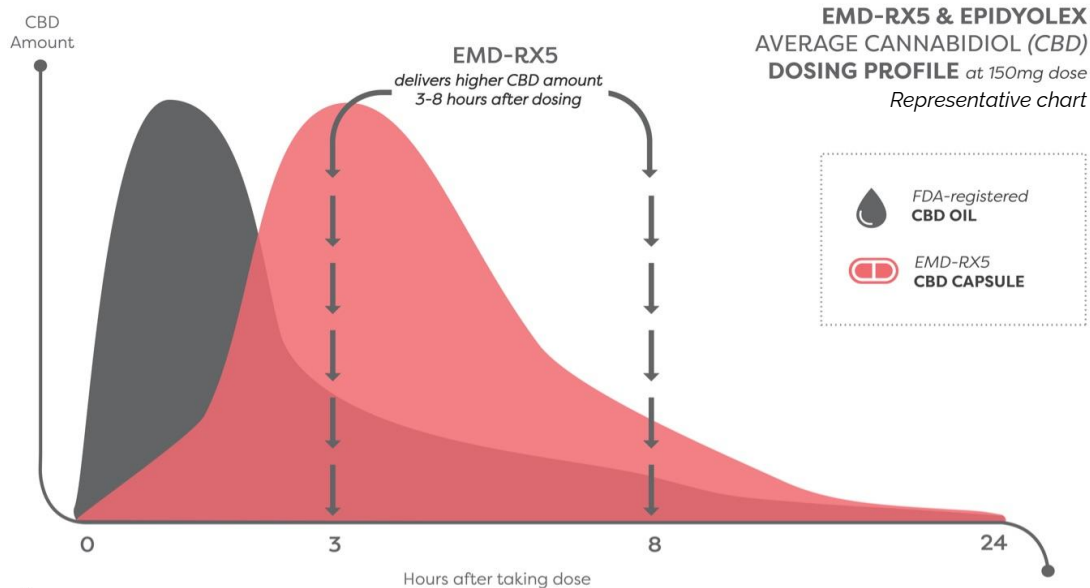


# EMYRIA HAS CREATED ITS FIRST **SOLID ORAL DOSE FORM** (EMD-RX5)





# EMD-RX5 HAS AN EXCELLENT DRUG RELEASE PROFILE



**EMD- RX5**

DEMONSTRATES  
STRONG

**SAFETY**



**BIOAVAILABILITY**



**RELIABILITY**



# EMD-RX5 HAS EXCELLENT PURITY *(required for FDA)*



## Botanical CBD

**Vs**

## Ultra-Pure CBD



### BIOLOGICAL ACTION

Ultrapure CBD has **equivalent** physiological effects to botanical CBD [1]

### REGULATORY CONSIDERATIONS

Most CBD oils **do not** meet FDA requirements for CBD purity (*with exception of Epidyolex*)

FDA Drug Master File for API.  
Acceptance from major regulators

### PURITY

**Small quantities of THC**  
**Small quantities of impurities**

**No detectable THC**  
**No detectable impurities**

### INTELLECTUAL PROPERTY

Most generic oils have limited IP

**100% Emyria-owned**

### COST

Plant growth & extraction expensive

**Lower cost over long-term**

### ENVIRONMENTAL IMPACT

**Up to 45x CO2 emissions**  
**Up to 333x water consumption [2]**

**Lower energy requirements**

# ULTRA-PURE CANNABINOID MEDICINES

## EMYRIA'S ULTRA-PURE CANNABINOID TREATMENTS:

- Target indications informed by Emyria's Real World Data
- Formulated to meet FDA requirements
- Have excellent safety, tolerability and bioavailability
- Meet patient preferences for a solid, oral dose form



PLANNING PHASE



FAST TRACKED WITH  
REAL WORLD DATA



ACTIVE MODE



COMPLETE

## CLINICAL PROGRAMS

EMD-RX5

### Psychological distress

OTC treatment for symptoms of psychological distress (eg. mild anxiety, stress, sleep disturbance)

### Irritable Bowel Syndrome (IBS)

OTC treatment for the symptoms of IBS (eg. gastrointestinal upset, stress, discomfort)

EMD-RX7

### EMD-RX7 multiple medical conditions\*

An ultra-pure, prescription treatment for conditions requiring higher CBD doses

EMD-RX#

### Other novel cannabinoid formulations

Ultra-pure, high bioavailability cannabinoid treatments targeting unmet needs

DOSE DEVELOPMENT  
PRE-CLINICAL

CLINICAL DEVELOPMENT PROGRAM  
PHASE 1 : PHASE 2 : PHASE 3

REGISTRATION PROGRESS  
AUSTRALIA TGA : USA FDA



PLANNING



PLANNING



PLANNING



PLANNING



\* To be determined



# Commercialising **EMD-RX5**

# EMD-RX5 SCHEDULE 3 (S3) OVER THE COUNTER ('OTC') DRUG

**Emyria** plans to register one of the first, affordable, cannabinoid S3 medicines in Australia (**EMD-RX5**) [1].

Emyria's unique formulation, backed by Real World Data (RWD) then allows pursuit of:

- **Additional clinical indications**
- **USA registration**
- ***Partnerships with major pharma***

## Commercialisation strategy

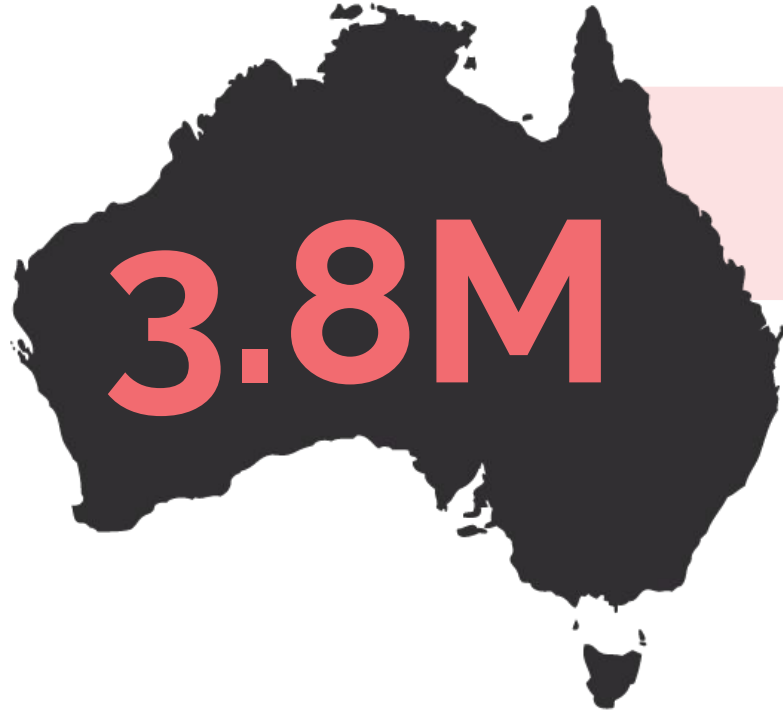
**5,900** pharmacies in Australia [2]. OTC market estimated at over **\$20B/year** [3].

**S3 cannabinoid medicines** could generate an estimated **\$200M** per year in Australia alone [4].

**EMD-RX5 is an FDA-compliant dose form allowing pursuit of US registration opportunities.**

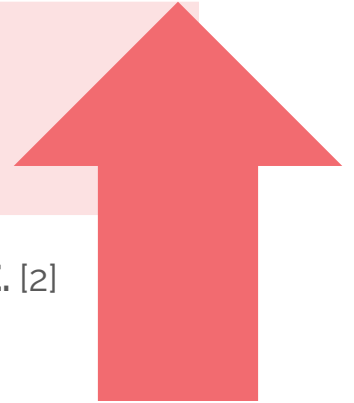


# PSYCHOLOGICAL DISTRESS - A GROWING PROBLEM



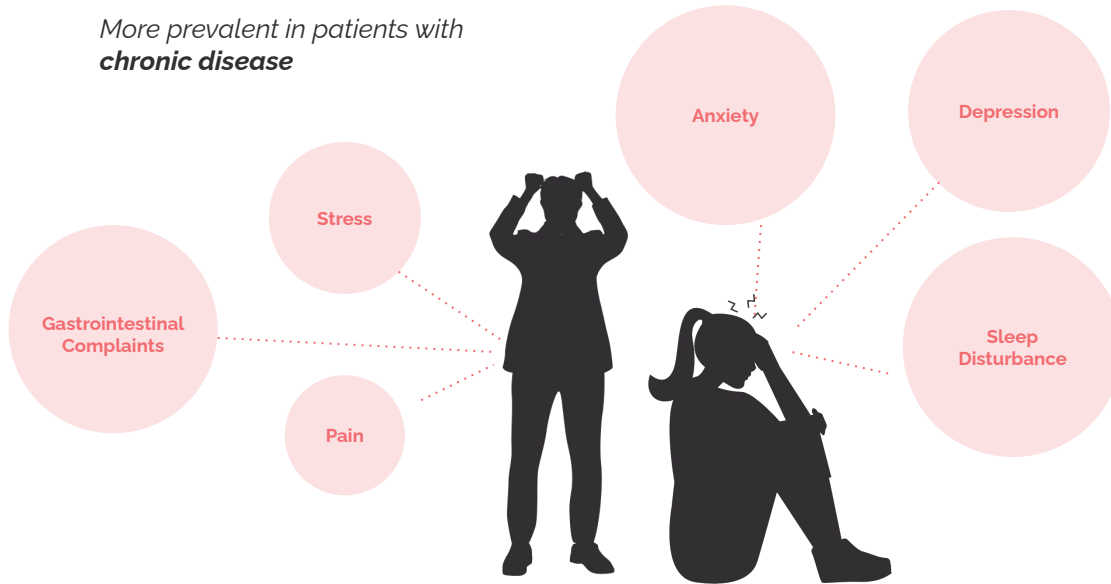
Australian Adults experience **HIGH** or **VERY HIGH** levels of psychological distress [1]

**AND** it's prevalence is on the **RISE**. [2]



# PSYCHOLOGICAL DISTRESS - SYMPTOMS & TREATMENTS

*More prevalent in patients with  
chronic disease*

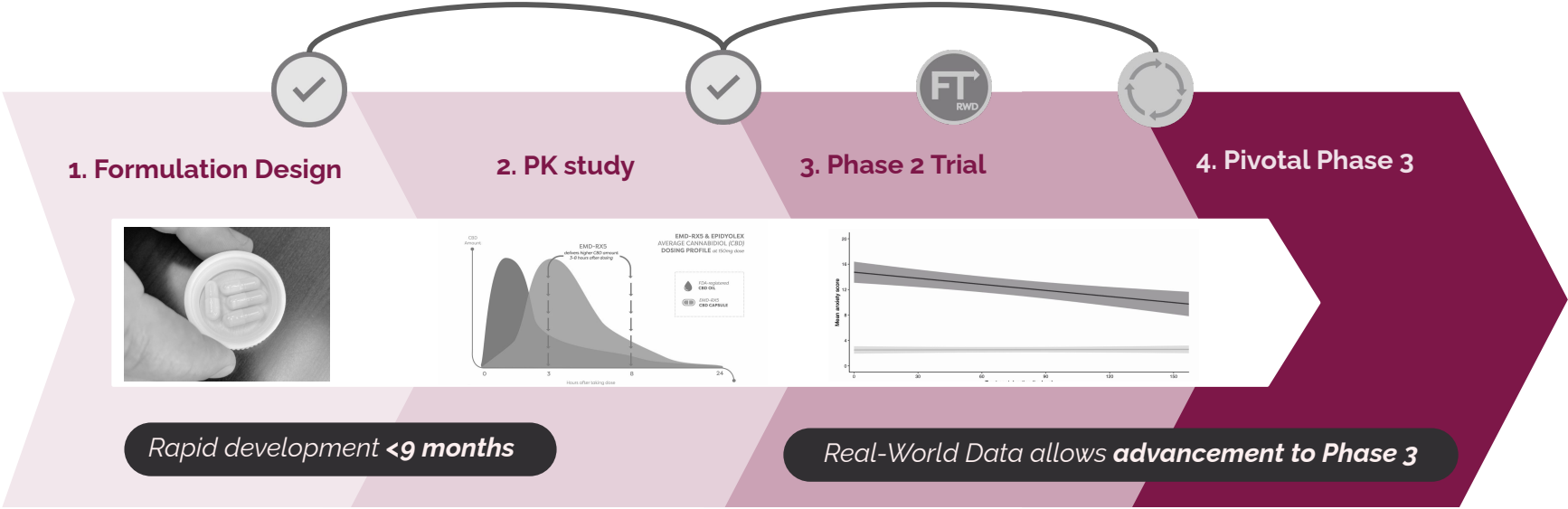


**Current treatments** may include:  
Monitoring, psychotherapy, prescription  
medications or , referral to support services. [1]

There is **NO over-the-counter**  
treatment for Psychological Distress



# ACCELERATED DRUG DEVELOPMENT FOR EMD-RX5



August 2021

May 2022

Expected Q2 2022

# UPCOMING PIVOTAL PHASE 3 STUDY

## Phase 3 - Efficacy & Safety

### Randomised Placebo Controlled Double Blind Trial

EMD-RX5: n = ~200 | Placebo: n = 110

Patients with Pain & Stress

Study time per patient ~ 8 wks

Each patient to have 4 weeks treatment, 4 weeks follow-up

5-6 sites around Australia already selected

Emerald Clinics to accelerate recruitment

CRO and Regulatory consultants engaged



Leading next-generation  
**Psychedelic Development**

# PSYCHEDELIC-ASSISTED THERAPY

Addressing **MAJOR UNMET NEEDS** & attracting **LARGE INVESTMENT**



**\$100b**

Estimated market for psychedelic medicines



**264m**

Number of people who suffer depression globally



**\$10.2b** (AUD)

Aggregate market cap of psychedelic drug companies



**2 in 3**

Veterans suffer from PTSD



**1 in 4**

People in the world are affected by mental health disorders

**cg/**Canaccord  
Genuity



**yahoo!**  
finance

**Cohen Veterans  
Network**



**Emyria's Real World Data model can help accelerate drug development**

# MDMA-LIKE MEDICINE DEVELOPMENT PARTNERSHIP

Entire library exclusively optioned to Emyria

with

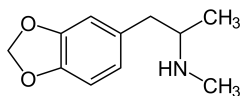


*MDMA as  
Inspiration*

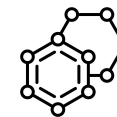
**Growing Library**  
(100+ proprietary analogues)

**Screening**  
(In vitro & In vivo)

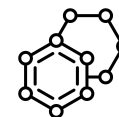
**Treatment  
Development**



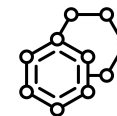
- Safety screens
- Prosocial effects
- Metabolism studies
- Peripheral effects



Next-gen MDMA



Neuropsychiatric  
treatments



Non-neurological  
treatments

# MDMA-LIKE MEDICINE DEVELOPMENT PARTNERSHIP

Entire library exclusively optioned to Emyria

with



## THE MDMA ANALOGUE LIBRARY

### WHY MDMA? KEY FEATURES OF LIBRARY

- **>100** unique MDMA analogues, *and growing* [1]
- **>10 years of development** at UWA
- Small molecules cross blood-brain barrier
- Verified **excellent purity and stability**
- Potential as treatments for:
  - ❑ Next-gen psychedelics,
  - ❑ neurological disorders
  - ❑ + *other conditions*

### PROGRESS TO DATE

- No "off-target" effects in first screens (*~85 compounds*) [2]
- First patent family filed
- Library expansion underway
- University of Sydney approached to develop animal models [2]

**NEXT:** *Further expansion, screening and evaluation*

# MDMA-LIKE MEDICINES (“MDMA ANALOGUES”)

With partner, the University of Western Australia, Emyria is creating a one-of-a-kind library of unique compounds inspired by -3, 4 -Methylenedioxyamphetamine (*also known as “MDMA” or “ecstasy”*).

**ADVANCED CLINICAL AND IP DEVELOPMENT STRATEGY** focussed on identifying novel small molecules with potential to become registered treatments as:

- Next-generation psychedelic-assisted therapies
- Novel neurological and non-neurological therapies



PLANNING PHASE



FAST TRACKED WITH  
REAL WORLD DATA



ACTIVE MODE



COMPLETE

## THERAPEUTIC FOCUS AREA

**Next-generation MDMA Targeting** PTSD  
psychedelic-assisted therapies  
neurological disorders (Parkinson's)  
non-neurological disorders

PRE-CLINICAL  
NEW COMPOUND : ADV. SCREENING



CLINICAL DEVELOPMENT PROGRAM  
PRE CLIN. TRIALS : LEAD SELECTION : CLIN. TRIALS



PLANNING



REGISTRATION PROGRESS  
AUSTRALIA TGA : USA FDA





# EMYRIA'S GROWING PATENT PORTFOLIO

	TITLE	OFFICIAL NO.	STATUS
	Use of Cannabidiol for the Treatment of Psychological Distress	2020904152	Provisional filed
	Use Of Cannabidiol for the Treatment of Psychological Distress	2021901086	Provisional filed
	Use Of Cannabidiol for the Treatment of Irritable Bowel Syndrome Symptoms	2021901672	Provisional filed
	Use Of Cannabinoid Combination for the Treatment of Irritable Bowel Syndrome Symptoms	2021901674	Provisional filed
	Cannabidiol Dosing Regime	2021902001	Provisional filed
	Cannabinoid Dosage Form	2022900479	Provisional filed
	Analogues	2021903836	Provisional filed
	<i>Others in development covering unique delivery platforms, dose responses and clinical indications</i>	<i>Multiple provisionals expected 2021</i>	

# EMYRIA IS POSITIONED FOR GROWTH

1

**World-class team**  
with FDA registration successes

**In-house expertise** in drug development, clinical trials and drug registration

2

Proprietary **data**, access to **clinics & patients**

One of the **largest Real World Data** assets on cannabinoid treatments guiding clinical development programs

3

Pursuing **multiple drug registrations**

**Multiple clinical programs** targeting major, unmet needs

4

Ultrapure **cannabinoid dose forms in clinic**

FDA-compliant ultrapure CBD with **dose profile advantages**

5

Exclusive access to multiple **MDMA-like leads**

**Advancing novel MDMA analogues** through preclinical screening

6

Attractive **valuation & register**



## CONTACT INFORMATION

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