

emyria

(ASX:EMD)

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

January 2023 |

Biotech Showcase, San Francisco

Michael Winlo, MBBS(Hons), MBA



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Presentation release authorised by Michael Winlo, CEO and Managing Director

emyria

An Australian
public biotech
company listed on
the Australian
Stock Exchange

(EMD:ASX) 2019

CLINICAL FOCUS

Neuroscience & mental health



COMPARATIVE ADVANTAGES

- **Proprietary Real-World Data** co-created w. patients in Palantir Foundry
- **A specialist clinical service** (*Emerald Clinics*)
- **Unique drug formulations**
- **Proprietary MDMA-inspired novel chemical entity library**
- **Global leadership team & partners** with drug registration successes

LEADING PROGRAMS & TRACTION

CLINICAL: ULTRA-PURE CANNABINOID MEDICINES

- Proprietary “RX” platform improves the bioavailability, release profile, safety & tolerability of cannabinoid-based medicines
- Supports multiple global drug registration opportunities; FDA-ready
- *First dose form (EMD-RX5) in **Phase 3 clinical trials** (ACTRN: 12622001319763)*

PRECLINICAL: MDMA-INSPIRED MEDICINE DISCOVERY

- One of world’s largest libraries of unique entities inspired by MDMA
- Partnership with Prof Matt Piggott, world recognised expert in amphetamine chemistry, from University of Western Australia
- ***Preclinical program commenced*** with global leaders

IP & PROTECTION

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

EMYRIA'S MODEL DE-RISKS AND ACCELERATES DRUG DISCOVERY

CLINICAL SERVICES → THAT CREATE... → DATA ASSETS (with validated assessments) → TO SUPPORT...

GMP-grade, cannabinoid-based medicines

WHY? Patients not responding to standard of care are interested in cannabinoids but evidence is lacking for alternative indications.

THE OPPORTUNITY Create a reliable Ultra-Pure product that meets FDA registration standards **backed by** high quality clinical evidence to support multiple registration opportunities.

8,000+ PATIENTS
(and growing)

DATA SUPPORTS
"dose-response"
analysis

DRUG DEVELOPMENT

EMD-RX5 - Low dose CBD for over-the-counter indications. In **Phase 3**.
Over 100 patients pre-screened to date.

EMD-RX7 - High dose CBD pursuing prescription indications with FDA via 505(b)2.

Others - in development

MDMA-assisted therapy *(in planning)*

WHY? MDMA is likely the **first** psychedelic - assisted therapy to obtain FDA registration. [1]

THE OPPORTUNITY: Create an evidence-generating service providing safe patient access & creating robust clinical data to support service innovation and new drug development.

PHASE 2B
OBSERVATIONAL TRIAL

DATA SUPPORTS
"patient selection",
cost-benefit analysis

TREATMENT DEVELOPMENT

Clinical delivery : Leverage learnings from cannabinoids to establish a scalable, evidence-generating clinical service

MDMA-
ANALOGUES

Drug discovery : Create novel analogues with potential to address a wider range of neuropsychiatric disorders

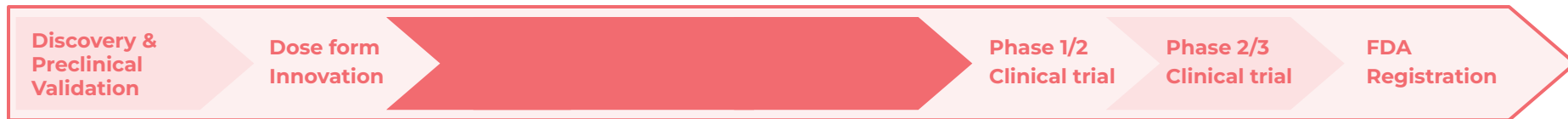
1. <https://maps.org/mdma/ptsd/mapp2/>

EMYRIA'S MODEL DE-RISKS AND ACCELERATES DRUG DISCOVERY

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



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



Real-World Data insights from **8,000+ patients** Informs indication selection and trial design

Ultra-Pure Cannabinoids

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



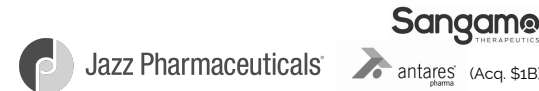
Prof Sir John Tooke
Non-Executive Director &
Chair of the Risk Committee
FRCP, FMedSci

- 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



CLINICAL AMBASSADORS | GLOBAL EXPERTS IN NEUROSCIENCE AND PSYCHIATRY



Dr Jen Morgan (St. Johns)
Anaesthetist & Pain Specialist
MBBS, FRANZCA

- Specialist anaesthetist
- Pain medicine specialist
- Research collaborator with Emyria



Dr Richard Magtengaard
Consultant Psychiatrist
MBBS , BSc , RAN , RTD , FRANZCP

- Psychiatry
- Ex-Naval Officer Australian Navy
- Advisor to DVA



Ass/Prof. Sara Ward (Temple University)
CIPN Expert
PhD

- Professor neural sciences
- Preclinical researcher in CIPN
- Cannabinoid expert



Dr Jeremy Tannenbaum
Consultant Pain Specialist Consultant Psychiatrist
BSc, MBBS (Hons), FRANZCP

- Dual specialist in psychiatry and pain medicine
- Research into psychedelics and related medicines



Dr Phil Finch
Pain Specialist
MBBS, FRANZCA

- Pain medicine specialist
- Cannabinoid authorised prescriber
- Research collaborator with Emyria



Prof Mat-Martin Iverson
Neuropharmacologist
Professor, BSc Alta., PhD Br.Col.

- Psychoneuropharmacology expert
- Emeritus professor at UWA
- Amphetamine research specialist



Dr Bill Bosch
Formulation specialist
PhD, BA

- Co-inventor of the SoluMatrix™
- 3 FDA approved products
- Experienced bio-pharmaceutical executive

CAPITAL STRUCTURE

TOP 20 – 60.48%
 **Tattarang** – owns ~7.8%
DIRECTOR OWNERSHIP – 27.17%

KEY METRICS	VALUE
Market Capitalisation	~A\$50M
Last reported cash (at 30 Sep 2022)	A\$2.2M + A\$3m raise completed [1] + A\$2m+ R&D cash refund

1. See ASX announcement 31 October 2022

ADVANCED CANNABINOID DEVELOPMENT



EPIDYOLEX™ | THE WORLD'S ONLY GLOBALLY REGISTERED CBD OIL

Despite hundreds of CBD products available, only 1 product has demonstrated the **clinical effectiveness** and **product reliability** required to achieve registration with major global regulators (like the FDA), driving significant value for shareholders

1998

Since 1998, GW Pharma has invested **>\$2B** and run **>50 clinical trials** [1]



2018

FDA approved Epidyolex for rare seizure disorders. Evaluated as a **“small molecule”** not **“botanical”** [2]



2021

GW **acquired** by Jazz Pharma for **USD \$7.2B** [3]



Jazz Pharmaceuticals to Acquire GW Pharmaceuticals plc, Creating an Innovative, High-Growth Global Biopharma Leader (February 3, 2021)

KEY INSIGHTS

- (1) Drug registration creates value but, requires
- (2) Great evidence (*Real-World Data*) and
- (3) Great products (*Ultra-Pure cannabinoids*)

We believe emyria can improve on Epidyolex oil & accelerate multiple new drug registrations

TIGHTER CBD REGULATION LIKELY IN USA AND EUROPE

Cannabidiol novel food evaluations on hold pending new data

7 June 2022



EFSA's scientists cannot currently establish the safety of cannabidiol (CBD) as a *novel food* due to data gaps and uncertainties about potential hazards related to CBD intake.

FDA, Concerned About Safety, Explores Regulating CBD in Foods, Supplements

Agency, which is studying the effects of cannabis-derived ingredients, aims to reveal its oversight plans in the coming months

By Liz Essley Whyte • Updated Dec. 29, 2022 at 6:13 pm ET



Only the most *reliable* products with the best clinical EVIDENCE will win market share.

EVIDENCE GENERATION

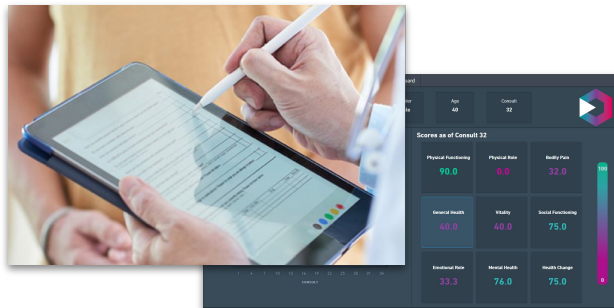


Emyria's national clinical service and **remote monitoring technology** generates evidence with patients to inform drug development and care delivery.



EVIDENCE-GENERATING CARE GUIDING DRUG DEVELOPMENT

Emyria's clinical service subsidiary, Emerald Clinics, provides care while generating evidence with patients on cannabinoid treatment. Emyria analyses this data to learn **what treatments work best, for which clinical problems and in which patients.**



A national specialist service with

- 8 GPs
- >400 referring specialists

8,000 patients and growing:

- Ages 2-98 years
- 40+ clinical indications
- Thousands of assessments per month

Millions of data points captured to understand each patient's clinical journey

Custom-built and evolving data pipeline supported by *Palantir Foundry*

Validated assessments covering:

- Symptom response
- Clinician assessments
- Quality-of-life surveys
- And many more

Emyria's Real-World Data helps answer:

- What clinical indications and symptoms respond best to treatment?
- What dosages work best for which patient groups?
- What are the long-term safety and efficacy considerations?
- What dose forms do patients prefer?

WORLD'S LARGEST REAL-WORLD DATA SET (RWD) ON CANNABINOIDS

Emyria's comprehensive RWD is a proprietary source of clinical insights and evidence that supports our cannabinoid drug development programs.



Read full article [here](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0272241)

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0272241>

“Psychological Distress affects a high proportion of patients. Cannabinoids can help”

Emyria's Real World Data provides unique insights for where cannabinoid treatment is most effective across a range of important, unmet clinical indications. **Each of these indications presents an opportunity for Emyria to develop a registered medication.**

SYMPTOMS OF PSYCHOLOGICAL DISTRESS AFFECT MANY EMERALD PATIENTS

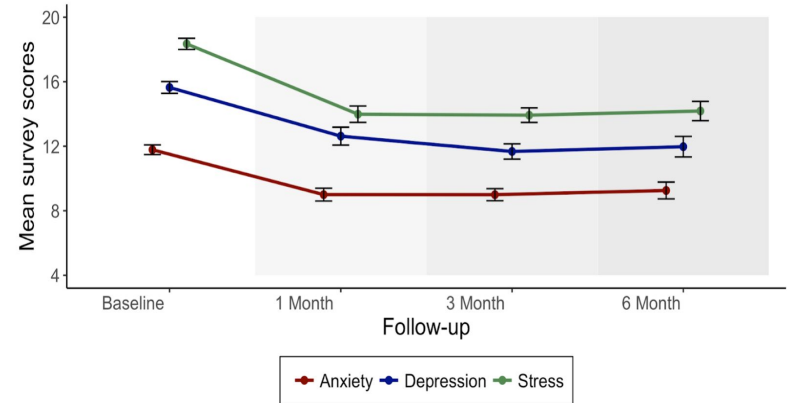
% of patients experiencing “mild” to “severe” symptoms of **psychological distress**

TOP 10 indications treated at Emerald Clinics

	ANXIETY ¹	DEPRESSION ¹	STRESS ¹	INSOMNIA ²
Chronic non-cancer pain	73	52	39	60
Insomnia	76	49	42	95
Cancer pain	75	37	24	75
Anxiety	57	70	73	85
PTSD	42	82	76	95
Autism	68	54	80	77
Depression	76	71	67	83
Migraine/headache	74	44	40	84
Irritable bowel syndrome	62	45	42	85
Parkinson's disease	59	52	43	89

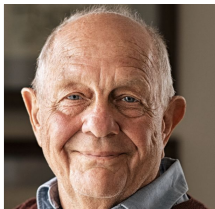


SELECT CANNABINOIDS CAN IMPROVE SYMPTOMS OF PSYCHOLOGICAL DISTRESS IN SELECT PATIENT COHORTS



KEY OPPORTUNITY

TO CREATE A RELIABLE CANNABINOID TREATMENT



CIPN CASE STUDY BEN

Ben is a 65-year old Vietnam 65 yoa Veteran (DVA) with persistent CIPN with bilateral peripheral neuropathy.

Bowel Ca 2012 - AP resection, Chemo (FOLFOX = folinate, 5-fluorouracil, oxaliplatin) CIPN hands and feet with numbness, tingling and burning neuropathic type pain, Associated severe depression, T2DM, PTSD, Low lumbar pain from vertebral fractures- war service.

PREVIOUS FAILED TREATMENT:

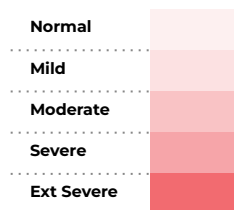
- **Medication:** Targin and Oxycontin up to 80mg bd, Pan forte, Tramadol, Tapentadol, Pregabalin
- Ketamine infusions x2
- Nerve blocks, back surgery

@ 10 MONTHS POST RX:

- Ongoing balanced THC/CBD
- Improvement in Pain control and improved sleep
- Reduction in opioids and weaning off pregabalin
- Depression improving

@ 20 MONTHS POST RX:

- Increased MC dose
- Less stress and anxiety, considerable improvement in mood
- Decreased oMEDD, and ceased pregabalin
- Peripheral neuropathy causing less pain and able to walk more comfortably in shoes
- Recurrence of bowel ca to re-commence chemo



	PROM	BASELINE (0 months)	F/U 9 (10 months)	F/U 13 (20 months)
Depression		40	28	26
Anxiety		34	26	22
Stress		40	24	20
Insomnia		25	13	8
Pain interference		9.4	6.3	5
Pain Severity		6	4.3	2.5
oMEDD (mg/day)		60 (240)	16	8
Pregabalin (mg)		450	150	0
CANNABINOID DOSE				
THC (mg/day)		-	15	22
CBD (mg/day)		-	15	30

PRODUCT DEVELOPMENT

EMD-RX PLATFORM

A world-first, proprietary formulation that delivers **Ultra-Pure cannabinoids** in a solid, oral dose form with high bioavailability to support multiple, global, **over-the-counter** and **prescription** registration opportunities.

MOST CANNABINOID PRODUCTS HAVE LIMITATIONS

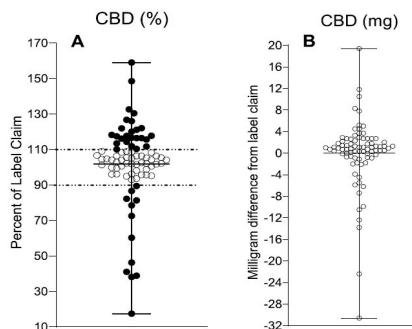
**CBD PRODUCTS ARE
UNDIFFERENTIATED**

There are more than



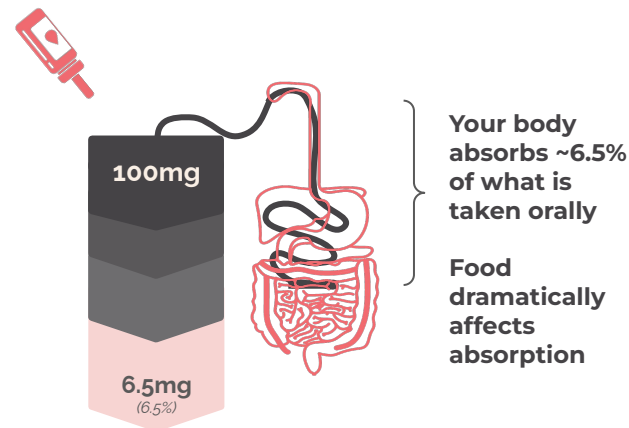
products in Australia,
most are undifferentiated.

**PRODUCT RELIABILITY
IS VARIABLE [1]**



What's
on the
label is
not in
the box

**BIOAVAILABILITY
IS POOR [2]**



KEY OPPORTUNITY

Emyria has developed a differentiated cannabinoid product that is:

1. Ultra-Pure (meets requirements for FDA registration) **2. improves bioavailability** in a **3. patient-preferred dose form.**

emyria

1. 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>

2. <https://www.tga.gov.au/sites/default/files/auspar-cannabidiol-210115.pdf>



EMD-RX

Vs

CBD oils
& similar preparations

PATIENT PREFERRED FORM

Convenient, solid oral capsules (no spilling)

Majority of products are oil preparations

ULTRA PURITY

No detectable *THC*
No detectable *impurities*Small quantities of *THC*
Small quantities of *impurities*

SAFE & TOLERABLE

Safe & well tolerated at trial doses
No observed gastrointestinal upset

Adverse events at higher doses (eg GI upset)

NOVEL IP

Proprietary formulation

Most CBD oils are “me too” products with generic formulations and limited IP protections

FDA-READY

FDA Drug Master File for API.
*Allows Emyria to reference material to regulator without disclosing contents [1]*Most CBD oils **do not** meet FDA requirements for CBD purity (*with exception of Epidyolex*) [2]

PREFERRED DOSING PROFILE

High bioavailability, low inter-patient variability & slow release

Poor bioavailability, high patient variability

AT CLINICAL STAGE

In Phase 3 clinical trials

Majority of products have no supportive trial data

KEY INSIGHT

Emyria's proprietary, FDA-ready dose form solves a number of limitations with common CBD preparations. EMD-RX5 is ready for multiple indications and global registration opportunities with demonstrated clinical performance.

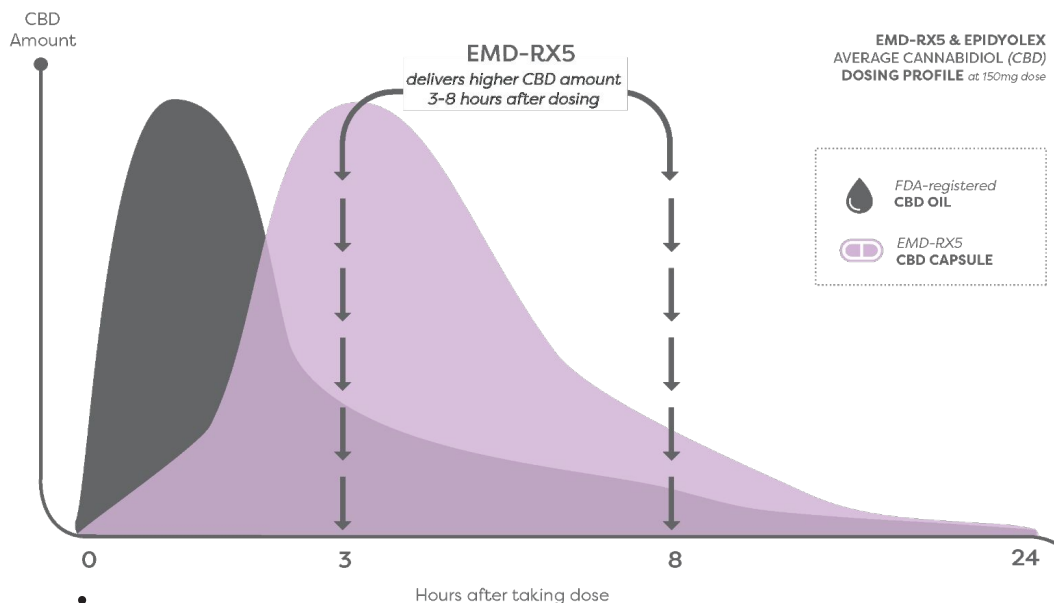
EMD-RX5

Emyria's first Ultra-Pure, low-dose CBD capsule is in Phase 3 trials and pursuing multiple, global "over-the-counter" registration opportunities



EMD-RX5 | ULTRA-PURE CBD CAPSULE VS EPIDYOLEX™ OIL

In less than 12 months, Emyria developed a proprietary Ultra-Pure CBD capsule and completed both animal and human trials.



Compared to Epidyolex, EMD-RX5:

Slower-release profile
(supports once to twice daily dosing)

Lower dose variability between patients
(more consistent drug exposure between patients)

Lower metabolite measures
(may contribute to improved long-term safety profile)

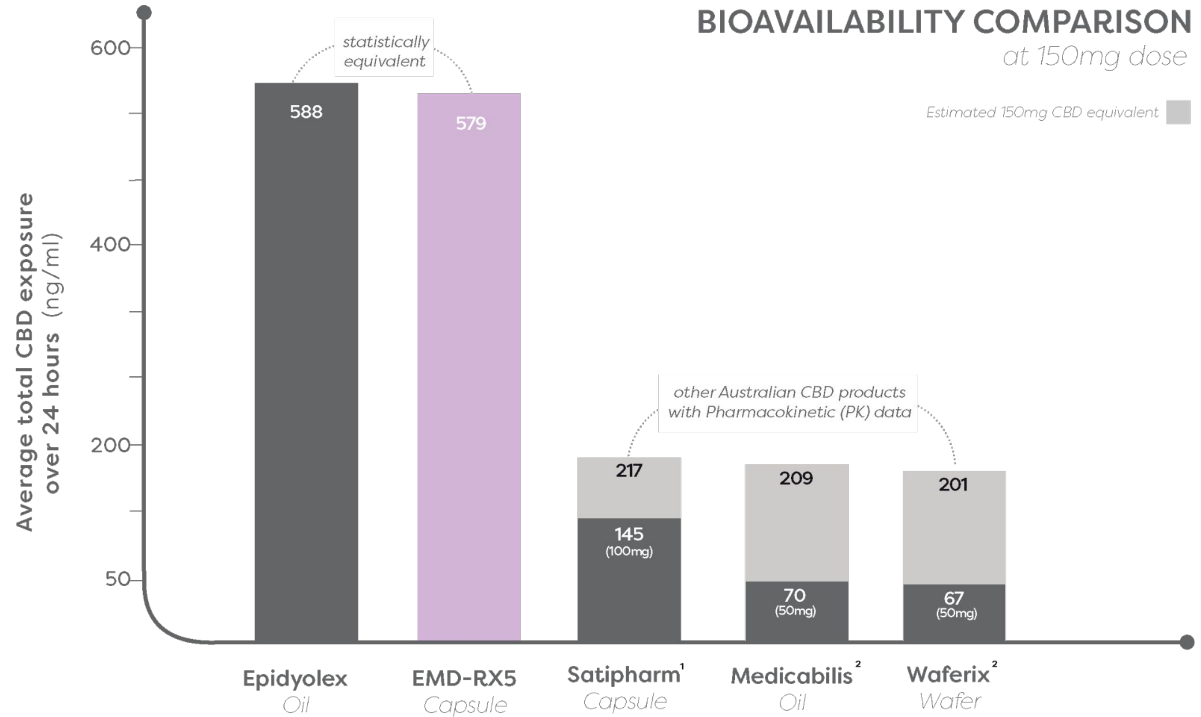
EMD-RX5:

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

Highly bioavailable

Safe and well tolerated
(no GI upset observed)

EMD-RX5 | ULTRA-PURE CBD CAPSULE VS EPIDYOLEX™ OIL and other products



EMD-RX5 | OVER-THE-COUNTER TREATMENT FOR PSYCHOLOGICAL DISTRESS

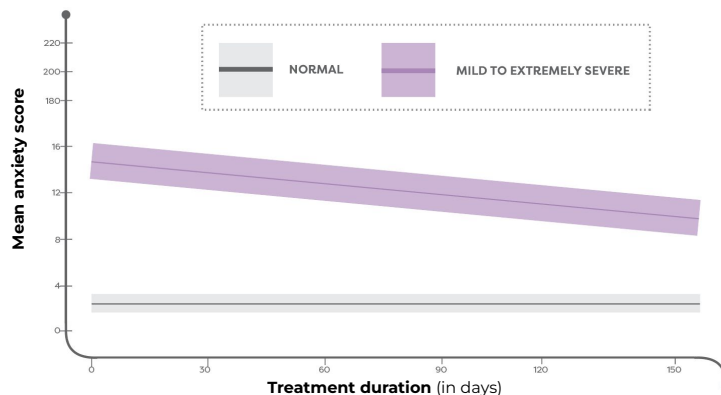
INITIAL CLINICAL / COMMERCIAL OPPORTUNITY



15% of adults experience **high** or **very high** levels of **psychological distress** & incidence is growing [1] **There is no OTC treatment today.**

Psychological distress comprises symptoms of anxiety, stress, sleep disturbance and GI upset with a **higher prevalence in chronic disease patients**

INDICATION SELECTION SUPPORTED BY RWD



To develop dose form and registration trial program, Emyria generated and evaluated data on more than 600 patients receiving low-dose CBD for 6+ months

UNIQUE DOSE FORM

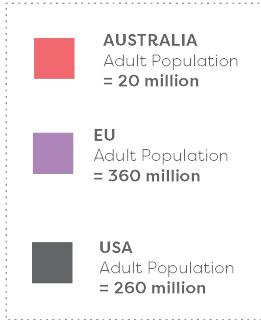
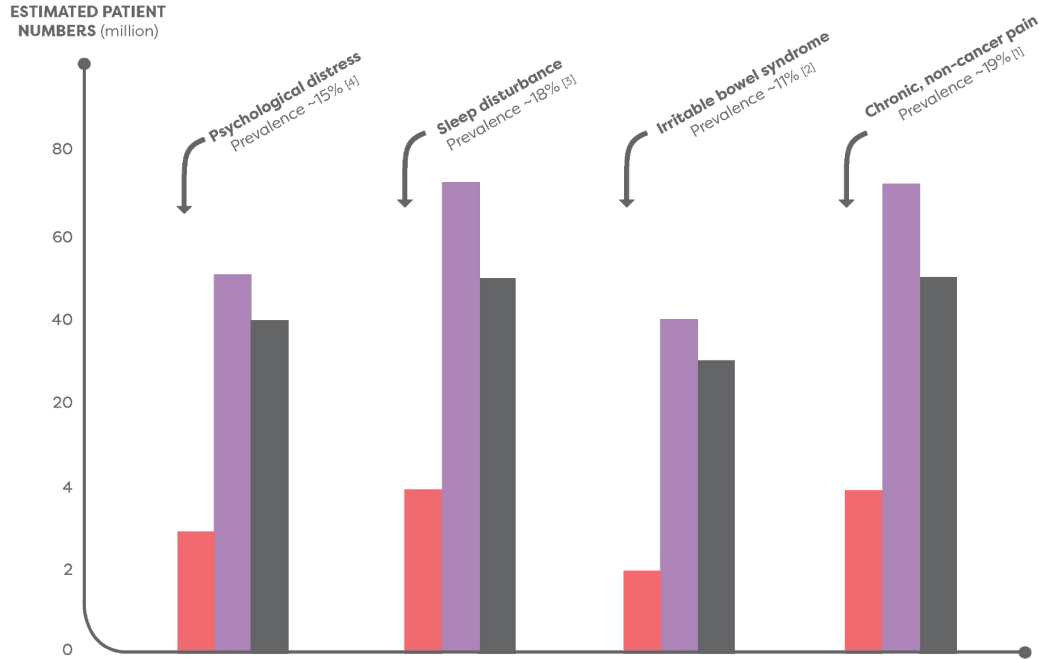


Proprietary formulation protects against generics

- Registered S3 treatments do not require a doctor's prescription. Australians spend **\$5b/year on OTC medicines** in pharmacies [2]
- On November 2020 the **TGA allowed low-dose CBD** to be registered as an "over-the-counter", pharmacist-only, Schedule 3 (S3) medicine. [3]
- Emyria filed multiple 'methods of use' patents to cover use of low-dose CBD across a range of appropriate indications.

EMD-RX5 | GLOBAL OVER-THE-COUNTER STRATEGY

An Ultra-Pure cannabinoid product makes it possible to pursue registration beyond Australia in jurisdictions where product purity rules are stricter. With the support of Emyria's proprietary Real-World Data, EMD-RX5 has multi-indication potential.



Emyria's Ultra-Pure dose form & Real-World Data supports growth through indication and geographic expansion.



1. See ASX announcement 16 December 2021 2. Canavan, C., West, J. and Card, T., 2014. The epidemiology of irritable bowel syndrome. Clinical epidemiology, 6, p.71.
 3. Grandner, M.A., Martin, J.L., Patel, N.P., Jackson, N.J., Gehrman, P.R., Pien, G., Perlis, M.L., Xie, D., Sha, D., Weaver, T. and Gooneratne, N.S., 2012. Age and sleep disturbances among American men and women: data from the US Behavioral Risk Factor Surveillance System. Sleep, 35(3), pp.395-406.
 4. National Study of Mental Health and Wellbeing 2020-21 series, Australian Bureau of Statistics

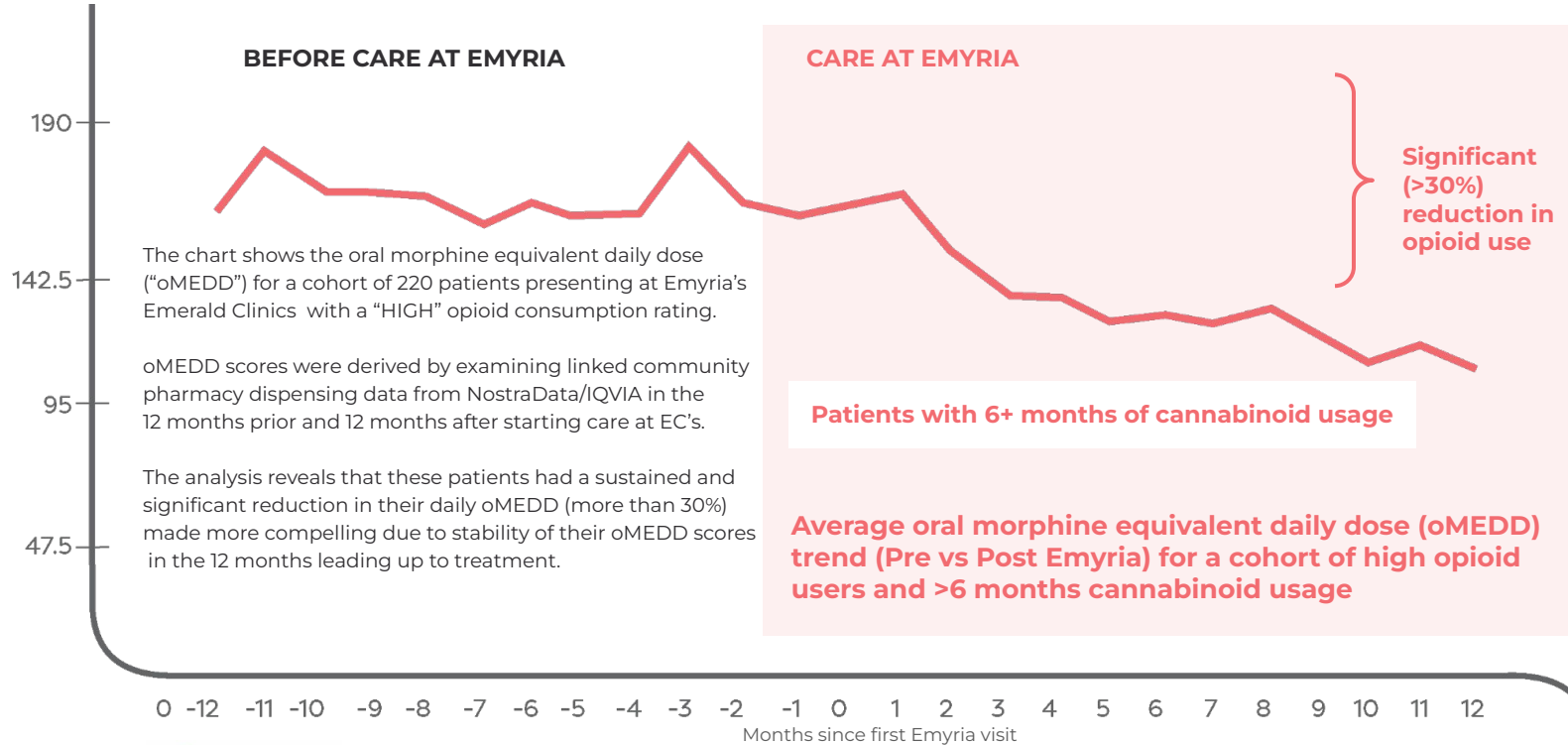
FUTURE

CANNABINOID TREATMENT DEVELOPMENT



CANNABINOIDS CAN REDUCE OPIOID USE BY 30%

Emyria's Real-World Data shows cannabinoids can help reduce opioid use in some patients. An Ultra-Pure product creates an opportunity to develop a registerable treatment for an important unmet need.



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

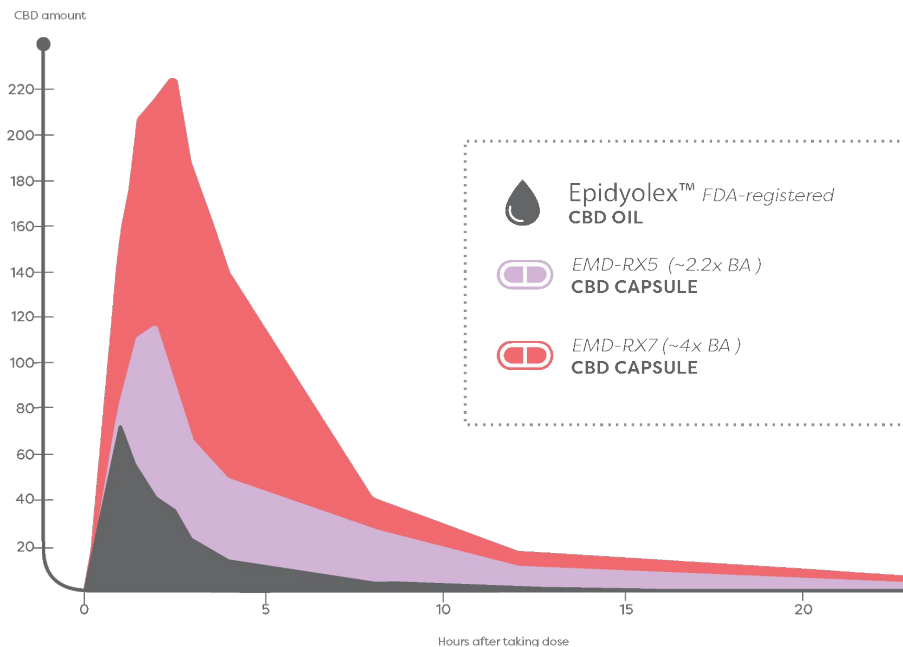


Chart shows concentrations of CBD in the blood for 3 different formulations as measured over a 24 hour period in an animal model.

Each formulation compared the same amount of CBD - 50mg.

EMD-RX7 showed more than 4 times the bioavailability of Epidyolex and is now being prepared for Phase 1 clinical trials to support prescription indications where higher doses of Ultra-Pure CBD are indicated. [1]

Emyria has been accepted into the NIH's preclinical screening platform for pain (PSPP) to further evaluate EMD-RX7 for pain indications. [2]

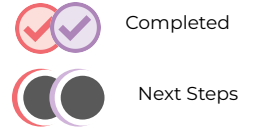
Additional, FDA-focussed indications are in planning via 505(b)2 pathway.



KEY INSIGHT

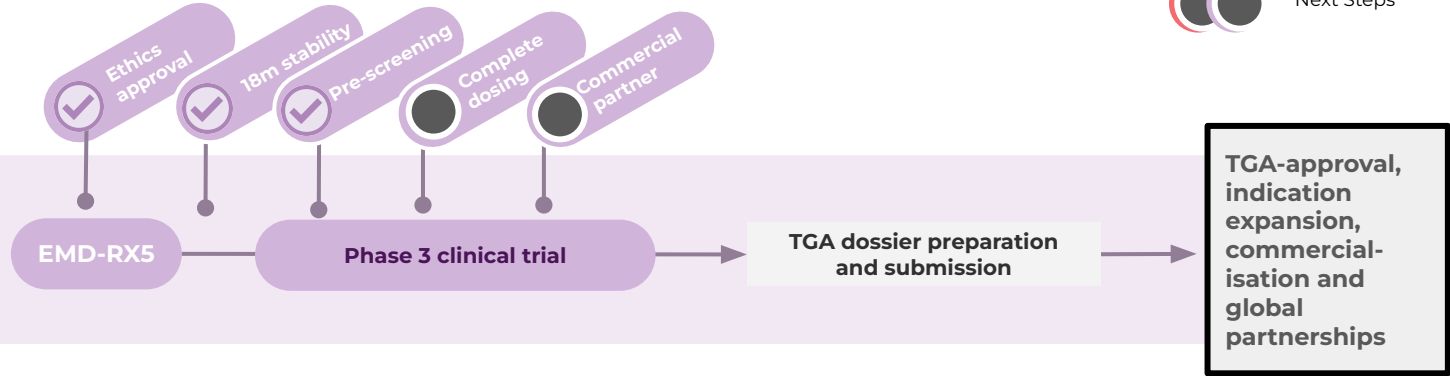
HIGHER BIOAVAILABILITY CBD has potential to support multiple, global prescription registrations

CANNABINOID DRUG DEVELOPMENT - WHAT'S NEXT?

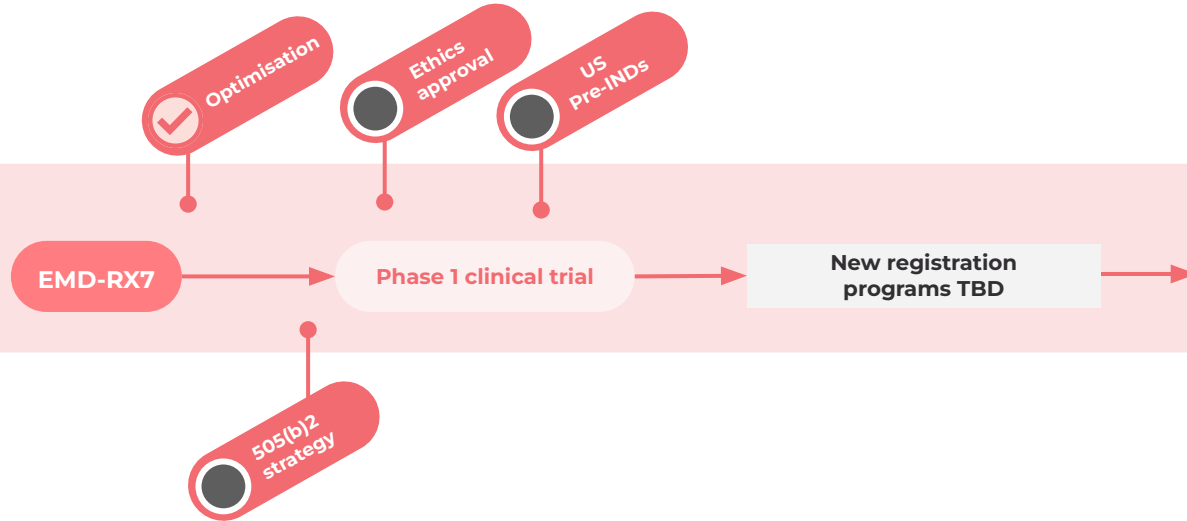


DRUG DEVELOPMENT

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



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



EMYRIA HAS DEEP INSIGHTS ON MORE THAN 40 INDICATIONS

Emyria has deep clinical insights on more than **40 clinical indications** creating a deep pipeline of future drug development opportunities.

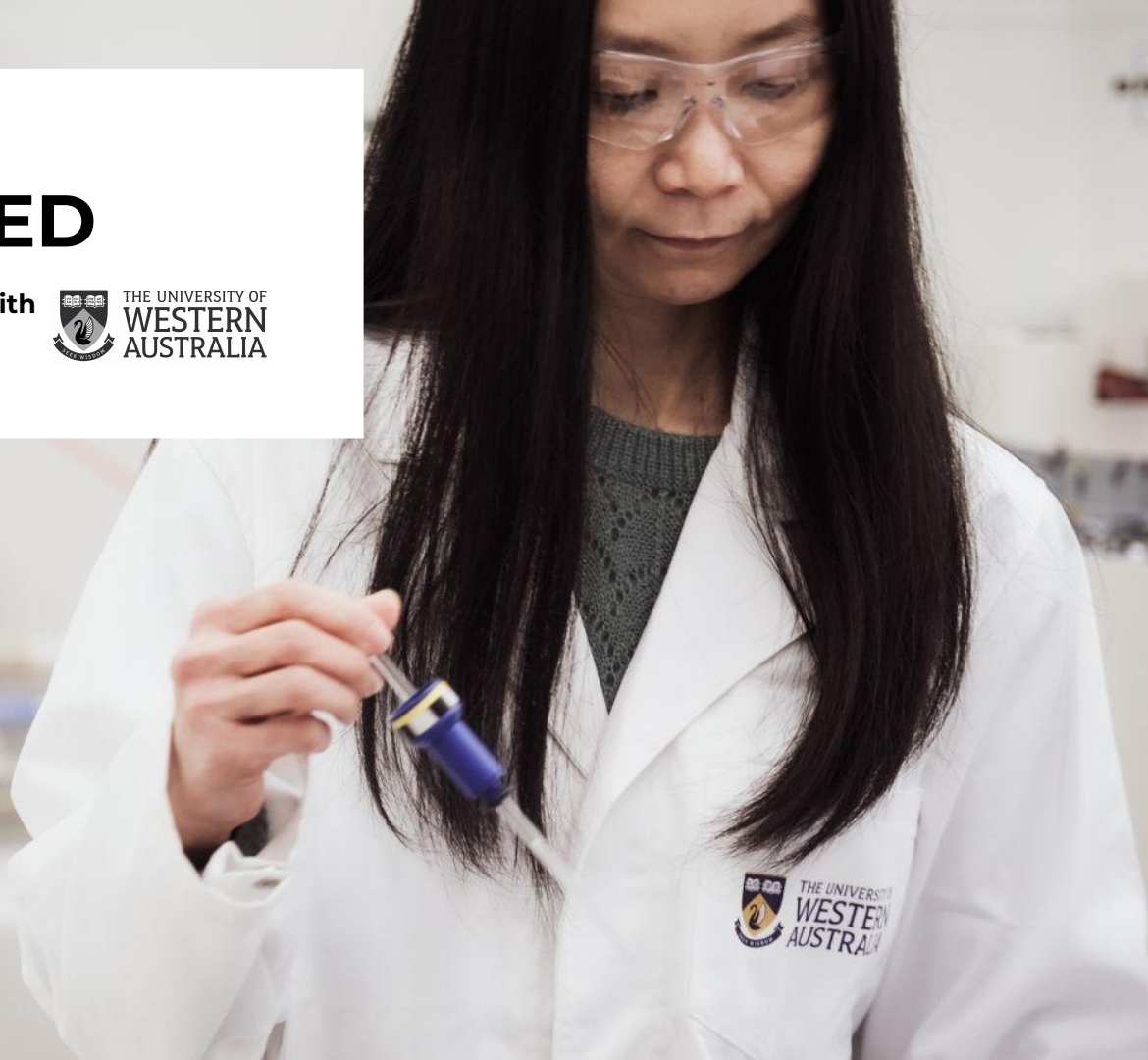
Alcohol use disorder	Chronic non-cancer pain	Insomnia	Post-traumatic stress disorder
Alzheimer's disease	Complex regional pain syndrome	Irritable bowel syndrome	Primary orthostatic tremor
Anorexia and wasting	Conversion disorder	Meniere's disease	Refractory nausea and vomiting
Anxiety	Dementia	Migraine/headache	Rheumatoid arthritis
Attention deficit hyperactivity disorder	Depression	Motor neuron disease	Spasticity
Autism	Endometriosis	Multiple sclerosis	Tinnitus
Behavioural disorder	Epilepsy	Obsessive compulsive disorder	Tourette syndrome
Cancer pain	Essential tremor	Panic disorder and benzodiazepine dependence	Traumatic brain injury
Cannabis use disorder	Hereditary spastic paraplegia	Parkinson's disease	Vaginismus
Chemotherapy-induced nausea and vomiting	Hypersalivation	Personality disorder	Vertigo
Chronic fatigue syndrome	Inflammatory bowel disease		

MDMA-INSPIRED

DRUG DISCOVERY with



THE UNIVERSITY OF
WESTERN
AUSTRALIA



The MDMA-PD CONNECTION

MDMA also alleviates LID in a primate model of PD

Iravani, et al. *J. Neurosci.* 2003, 23, 9107-15

DAY 1 L-DOPA + placebo

DAY 2 L-DOPA + ecstasy

WHAT IS **MDMA** (*3,4-methylenedioxyamphetamine* or “ecstasy”) ?

An illegal amphetamine that increases the release of 3 primary neurotransmitters:

1 Serotonin

thought to contribute to feelings of *well-being*

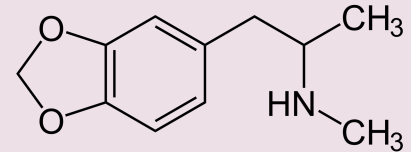
2 Dopamine

associated with feelings of *pleasure and satisfaction*

3 Noradrenaline

affects attention and related to “*fight or flight*” response

MDMA belongs to a class of drugs called “**empathogens**” or “**entactogens**” - drugs that produce experiences of *emotional communion*, oneness, relatedness, emotional openness—that is, empathy or sympathy.



WHY IS MDMA SUCH A PROMISING BACKBONE FOR NEW DRUG DISCOVERY?

NEW DRUG DISCOVERY

“Emyria is creating new chemical entities with the potential to become neuropsychiatric treatments”

MDMA and ITS ANALOGUES HAVE:

Privileged chemistry

- Small, stable and brain-penetrating molecules (*required for oral neurological drugs*)
- Many points of diversification (*lots of opportunity to create new chemical entities and IP*)

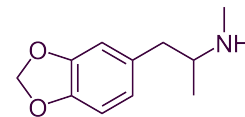
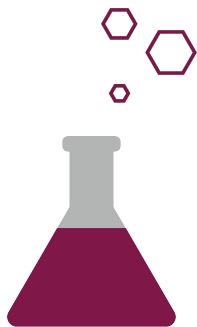
Neurologically active

- MDMA hits many brain targets (*opportunity to elicit different neurological effects*)
- Opportunities to tune selectivity

Promising therapeutic applications

- Increase receptiveness & positive mood (*next-generation MDMA assisted therapy*)
- Avoid potentially toxic metabolites
- Reduce stimulant amphetamine effects
- Moderate or remove euphoria

} (*safer treatments*)



MDMA INSPIRED DRUG DISCOVERY | WORKFLOW

NEW DRUG DISCOVERY

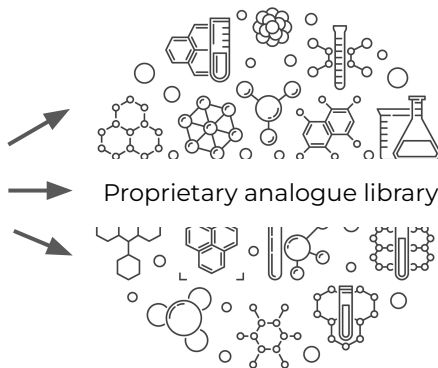
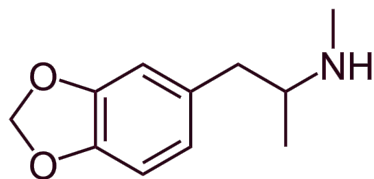


Take MDMA
as inspiration

Design and synthesise
new compounds

Screen analogues
(In vitro and In vivo)

Prioritise
indications



Proprietary analogue library

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



Mental health
(Next-gen MDMA)

Slides 32-35



Movement disorders
(Neuro treatments)

Slides 36-37



Non-neurological
(Fibrotic diseases)

Slides 38-39

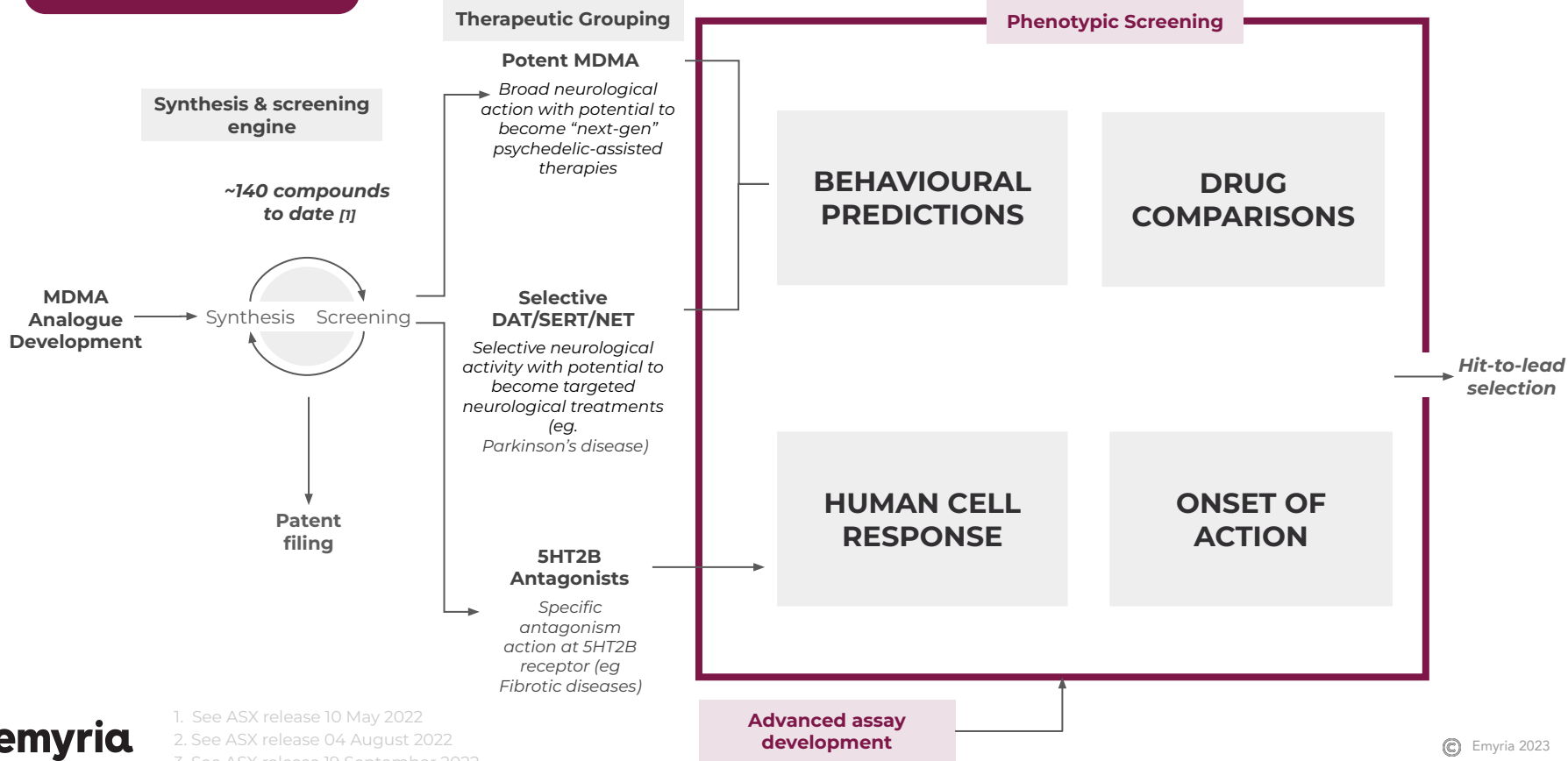
>140 novel chemical entities and growing

MDMA-INSPIRED DRUG DISCOVERY | EMYRIA'S EARLY RESULTS & EMERGING THERAPEUTIC LEADS

THERAPEUTIC CLASS	POTENCY REQUIREMENT	COMMERCIALISED EXAMPLES	# EMYRIA LEAD COMPOUNDS THAT MAY MEET POTENCY <i>(of first 19 leads evaluated, more in screening)</i>	NEXT EVALUATIONS IN PROGRESS
5HT2B antagonists	Antagonism of 5HT2B at 10 uM	<p>No approved treatments</p> <p>At least one private company developing drugs for this target exclusively (Anamar)</p>	3	
Dopamine reuptake inhibitors (DRI)	4-80x more selective for DAT over NET or SERT	Modafinil (Improve wakefulness in narcolepsy, OSA, or shift work disorder)	4	Human cell line assays
Norepinephrine reuptake inhibitors (NRI)	4-50x more selective for NET over DAT or SERT	<p>Edronax (Depression)</p> <p>Strattera (ADHD)</p> <p>Qelbree (ADHD, formerly depression)</p>	3	Functional release assays
Norepinephrine-dopamine reuptake inhibitors (NDRI)	4-25x more selective for DAT and NET over SERT	<p>Sunosi (Daytime sleepiness due to Narcolepsy /OSA)</p> <p>Ritalin (Narcolepsy, ADHD)</p> <p>Adderall (Narcolepsy, ADHD)</p> <p>Dexedrine (Narcolepsy, ADHD)</p>	8	Phenotypic drug discovery + metabolic screens
Serotonin-norepinephrine-dopamine reuptake inhibitors (SNDRI)	Nonselective DAT/SERT/NET binding (within 2.5x of each other)	Sanorex (originally approved for ADHD, discontinued)	1	

MDMA-INSPIRED DRUG DISCOVERY | ACTIVE PRECLINICAL WORKFLOWS

NEW DRUG DISCOVERY



MDMA INSPIRED DRUG DISCOVERY | WEBINAR

For a deep dive on our

MDMA-INSPIRED DRUG DISCOVERY PROGRAM go to:

<https://youtu.be/suZbQ3Bxuj8>

Or, take a look at our

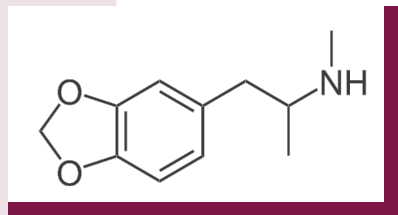
MDMA-INSPIRED DRUG DISCOVERY DECK

<https://wcsecure.weblink.com.au/pdf/EMD/02581678.pdf>



MDMA-Inspired Drug Discovery - Webinar - October 2022 - YouTube

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



Emyria-UWA MDMA analogue library captures a unique chemical space with differentiated pharmacology and novel IP

- **Largest reported database** of MDMA analogues currently in development with **>140 compounds** in the library (*and growing*) with demonstrated stability and purity
- **Compounds demonstrate diverse receptor binding profiles** on gold standard screening with positive preclinical proof-of-concept results suggesting the library has **broad clinical and commercial potential**
- **Current list of potential indications spans major unmet needs in:**

NEUROPSYCHIATRY

(Parkinson's, ADHD, narcolepsy, antidepressants, anxiolytics, antipsychotics, appetite suppression)



ANTI-FIBROSIS

(currently undergoing preclinical assays)

CLINICAL
OPPORTUNITIES



UNIQUE PSYCHO- PHARMACOLOGICAL | EFFECTS OF MDMA

Potential Target: MENTAL HEALTH

INCREASED



- feelings of wellbeing
- sociability and extroversion
- interpersonal trust

AN ALERT STATE OF CONSCIOUSNESS

DECREASED



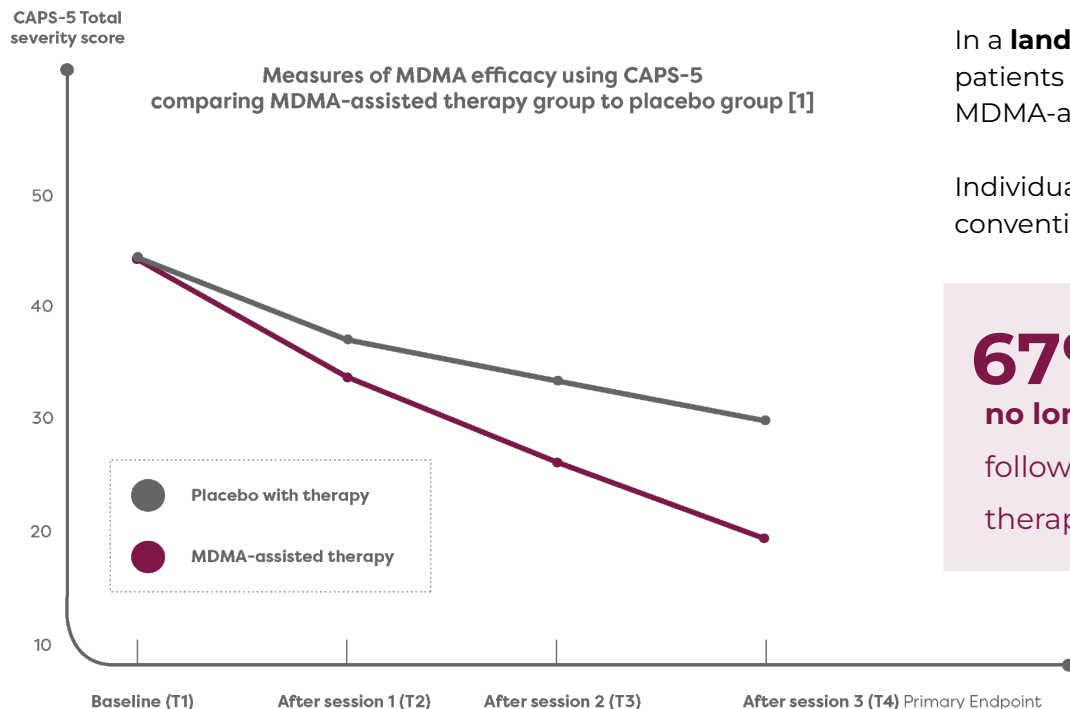
- feelings of fear & defensiveness



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

MDMA-ASSISTED THERAPY FOR **POST-TRAUMATIC STRESS DISORDER**

Potential Target: **MENTAL HEALTH**



In a **landmark Phase 3 study** (n=91) [1], patients with PTSD were randomized to receive MDMA-assisted therapy or therapy with placebo.

Individuals had severe illness refractory to all conventional treatment for an **average of 15 years**.

67% Of participants in the MDMA group **no longer met the PTSD diagnosis criteria** following treatment, compared to **32%** in the therapy-only group.

MAPS has recently completed second Phase 3 required to submit for FDA registration. [3]

1. Trial of MDMA-assisted therapy for severe PTSD, Multidisciplinary Association for Psychedelic Studies (MAPS), 2021
2. Mitchell JM, et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nature Medicine. 2021 Jun;27(6):1025-33
3. <https://mapspublicbenefit.com/press-releases/mapp2-completion-announcement/>

POST-TRAUMATIC STRESS DISORDER ¹ | MDMA-ASSISTED THERAPY

Potential Target: MENTAL HEALTH

Prevalence: 8.4m (but with a large, undiagnosed population of ~79%)

Treatment pattern: Benzodiazepines, antidepressants. High concomitant medication use.

Costs: ~USD\$25B/year (*direct medical costs*)

Unmet needs: Non-responders have few alternatives. There are subpopulations not served well by current treatments. Tolerability issues of current treatment in sensitive populations.



ROLE FOR MDMA?

MDMA-assisted therapy has been shown to greatly improve PTSD symptoms.²

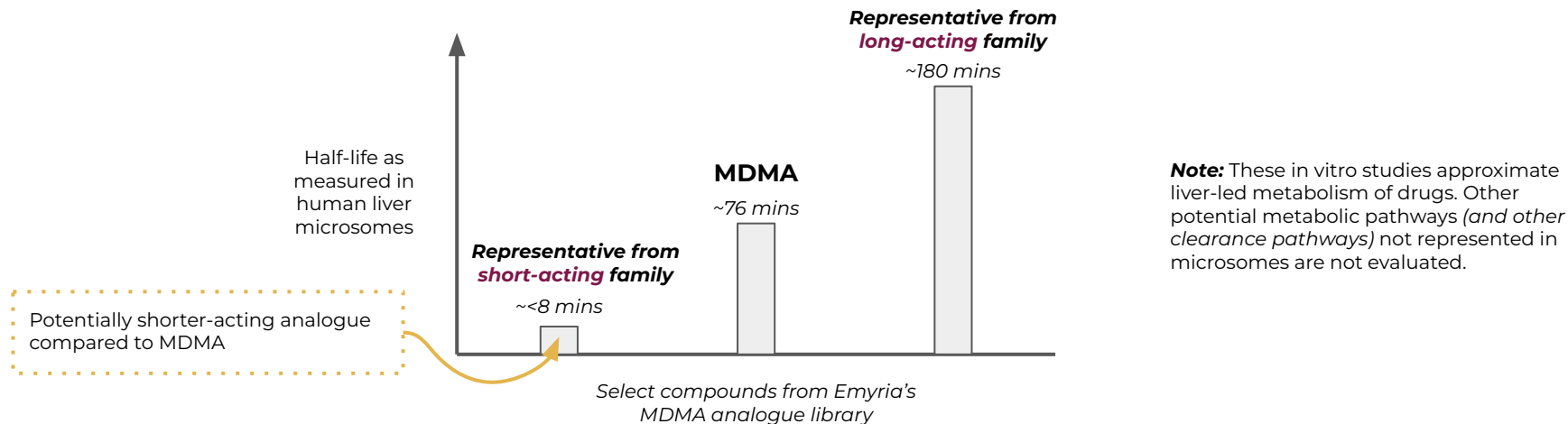
CLINICAL AND COMMERCIAL OPPORTUNITY FOR ANALOGUES?

MDMA-assisted therapy requires long sessions (6-12 hours). **Can we shorten the action of MDMA** to improve the delivery of this promising treatment in standard clinical practice?

POST-TRAUMATIC STRESS DISORDER | *shorter* MDMA-ASSISTED THERAPY?

Potential Target: MENTAL HEALTH

Recent in vitro metabolic studies of Emyria's analogues demonstrate that our library has compounds with diverse half-lives, suggesting it may be possible to generate MDMA analogues with much faster, and slower onset of action.



NEXT STEPS:

- Functional assays to identify novel compounds most like MDMA
- Further in vitro metabolic screening to approximate half-life

PARKINSON'S DISEASE ¹

Potential Target: MOVEMENT DISORDERS

Prevalence: 7m worldwide
(second most common neurological disorder after Alzheimer's)

Treatment pattern: Dopamine promoters (eg L-Dopa), antidepressants, cognition-enhancers, anti-tremor medications.

Costs: ~USD\$1B/year

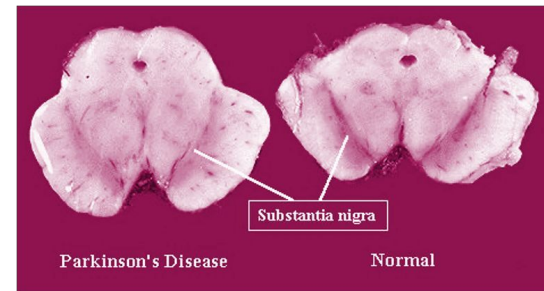
Unmet needs: Better control of tremor, gait and balance, posture, dexterity, and communication skills.
High incidence of L-Dopa induced dyskinesia (LID) in late stage.

ROLE FOR MDMA?

MDMA has been shown to improve L-dopa induced dyskinesia. ²

CLINICAL AND COMMERCIAL OPPORTUNITY FOR ANALOGUES?

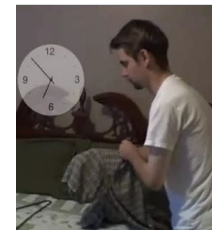
Can we preserve the movement benefits of MDMA but **remove the euphoria?**



Section of substantia nigra

PARKINSON'S DISEASE

is a neurodegenerative disorder that affects the dopamine-producing ("dopaminergic") neurons in a specific area of the brain called substantia nigra.

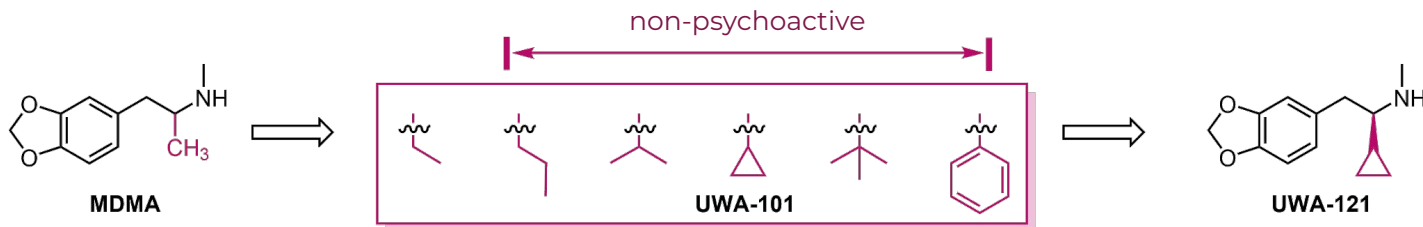


Patient with bradykinesia

The resulting symptoms of Parkinson's disease are typically slow movement (*bradykinesia*) and tremor.

PARKINSON'S DISEASE | Benefits of MDMA *without the high?*

Potential Target: MOVEMENT DISORDERS



- + Profoundly improves PD therapy (*i.e* increases “on time” of L-Dopa)
- Psychoactivity (*eg. euphoria, stimulant effects*) unsuitable for a chronic condition

Researchers at UWA created a series of non-psychoactive MDMA analogues; evaluated in rat and primate models of Parkinson's disease [1], [2]

A single enantiomer analogue (mirror image) was the most promising, non-psychoactive compound.

In a gold-standard PD primate model, UWA-121¹:

- **Extended** on-time by **40%**
- Increased **‘good quality’** on-time by **215%**

NEXT STEPS:

- Advance new compounds
- Evaluate long-term safety & durability

1. See ASX release 01 Sep 2021

2. A novel MDMA analogue, UWA-101, that lacks psychoactivity and cytotoxicity, enhances L-DOPA benefit in parkinsonian primates. FASEB J. 2012 May;26(5):2154-63. doi: 10.1096/fj.11-195016. Epub 2012 Feb 17. PMID: 22345403.

IDIOPATHIC PULMONARY FIBROSIS ¹

Potential Target: FIBROTIC DISEASE

Prevalence: 1.2m people worldwide

Treatment pattern: Anti-fibrosis drugs (Pirfenidone, Nintedanib), oxygen therapy, GI reflux medications

Costs: ~USD\$3B/year

Unmet needs: Reversing fibrotic changes, reduce side-effects of treatment

ROLE FOR MDMA?

MDMA analogues can induce fibrosis. Screening for this feature can reveal compounds with anti-fibrotic potential.

CLINICAL AND COMMERCIAL OPPORTUNITY FOR ANALOGUES?

Can we generate **MDMA analogues with strong antagonism at serotonin-mediated fibrosis pathways and reduce fibrosis?**

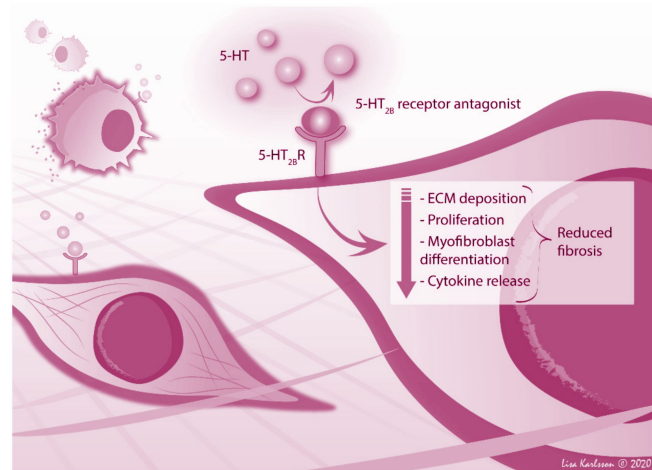
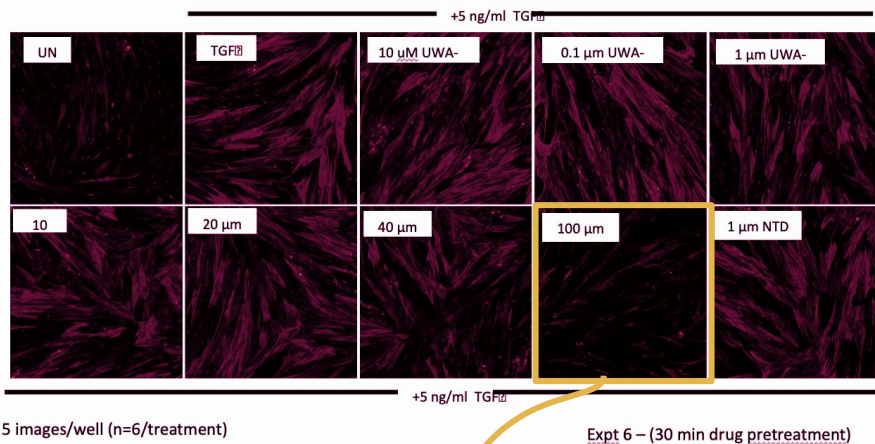


Figure: Shows anti-fibrotic cellular-signalling changes that may be initiated by **antagonism** at the 5HT_{2B} receptor.

IDIOPATHIC PULMONARY FIBROSIS | *5HT2B* ANTAGONIST POTENTIAL

Potential Target: FIBROTIC DISEASE

Myofibroblast Differentiation



Very early results suggest a reduction in collagen deposition at some test concentrations. Studies still ongoing and results need to be validated but promising early signal.

These preliminary in vitro screens, performed by the Institute of Respiratory Health,¹ measure the deposition of collagen (dark pink shapes) in human lung fibrocytes at varying concentrations of a test analogue.

These results show that, at a concentration of 100μm, the test analogue appears to suppress collagen. Compare with 1μm concentration of an approved antifibrosis drug, Nintedanib (NTD).

These results show fibrocyte suppression is possible and motivates further exploration of additional analogues and at varying concentrations.

NEXT STEPS:

- Continue human-cell line assays for additional analogues
- Competitive grant applications to support preclinical program

MDMA-INSPIRED DRUG DISCOVERY | WHAT'S NEXT?

NEW DRUG DISCOVERY

BACKED BY UWA RESEARCH

IN THE NEXT 12 MONTHS, EMYRIA INTENDS TO:

- **Deliver results** from multiple preclinical programs on select MDMA analogues
- **Select leads** by proof-of-concept efficacy studies in animal models
- **Expand** the MDMA-analogue library
- **File** additional patent families and pursue commercialisation discussions

MDMA-A

Ongoing creation and
in vivo screening

Hit-to-lead identification and dose form development

Preclinical Screening and Toxicology

Phase 1
Clinical Trials

CORPORATE & IP



EMYRIA'S GROWING PATENT PORTFOLIO



	TITLE	OFFICIAL NO.	STATUS
	Analogues	2021903836	Provisional filed
	Cannabidiol Dosing Regime	2021902001	Provisional filed
	Cannabinoid Dosage Form	2022900479	Provisional filed
	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
	<i>Others in development covering unique delivery platforms, dose responses and clinical indications</i>		<i>Additional provisionals expected</i>

MAJOR ACHIEVEMENTS & NEAR-TERM CATALYSTS

DRUG DEVELOPMENT

CLINICAL PROGRAMS

Ultra-Pure cannabinoid delivery platform

CORPORATE ACHIEVEMENTS	
Added bio-pharmaceutical executive to Board - Dr Karen Smith . Ex-Chief Medical Officer and Global Head of Research & Development at Jazz Pharmaceuticals. Dr. Smith has overseen multiple FDA registrations and participated in multiple, billion + dollar biotech mergers and acquisitions.	✓
Part of Tenmile's initial investment cohort - <i>Tattarang's Health Investment Fund</i>	✓
Invited to Palantir's Foundry for Builders program, boosting data integration and analysis capabilities	✓

EMD-RX5 "direct-to-consumer"	
Formulation optimisation	✓
Phase 1 study	✓
Ethics approved for Phase 3	✓
Phase 3 commencement	✓
Regulatory submission	
Commercial strategy Australia	
Commercial strategy Europe	
Commercial strategy USA	

EMD-RX7 "prescription medicine"	
Formulation optimisation	✓
Phase 1	
Pre-IND (FDA)	
Pivotal trials	

NEW DRUG DISCOVERY

PRE-CLINICAL PROGRAM

MDMA-like analogues

MDMA-like drug development	
Continuous creation & screening	✓
First patent family filed	✓
US-focussed preclinical program	✓
Metabolic studies	✓
Preclinical assays (<i>multiple animal models</i>)	✓
Human cell line assays	✓
Advanced functional assays	
Lead selection	
Phase 1 trials	
Global commercial strategy	

emyria INVESTMENT HIGHLIGHTS

1

Proprietary Ultra-Pure CBD formulations -

partnership ready

Demonstrated benefits over incumbent technologies.

No THC or impurities; **high bioavailability**; low patient variability & slow release.

Supports multiple dose forms & indications.

2

In phase 3 clinical trials

EMD-RX5: In pivotal **Phase 3 clinical trials** to support over-the-counter registrations.

EMD-RX7: Preparing for *Phase 1* trials, preclinical studies show 4x bioavailability compared to Epidyolex™.

3

Proprietary Real World Data (RWD)

Emyria's clinical service, **Emerald Clinics**, has gathered the world's largest data set with patients guiding indication selection, cannabinoid dose form development and pivotal clinical trial design.

4

Substantial R&D pipeline

One of world's largest MDMA analogue libraries - novel, small, stable, brain-penetrating and neuroactive molecules with potential to become novel neuropsychiatric treatments.

5

World-class team with multiple FDA registrations

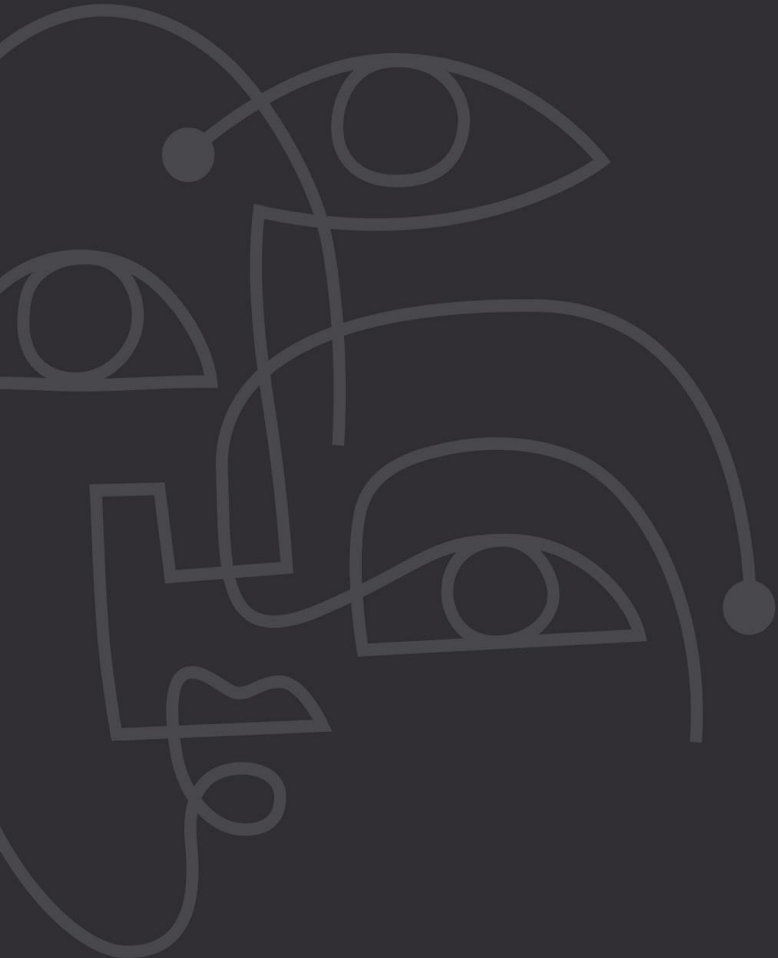
Emyria's in-house expertise covers drug development, clinical trials, drug registration, data analysis and patient care.

Accelerate the development of promising treatments where *evidence* is lacking **BY COLLABORATING WITH :**

PATIENTS to generate **CLINICAL DATA** & **GLOBAL EXPERTS** to create **NEW TREATMENT TECH** (*formulations & analogues*)

Register multiple treatments globally using our proprietary Ultra-Pure cannabinoid formulations, and guided by our Real World Data

Become a global leader in the development of multiple, novel neuropsychiatric treatments inspired by MDMA



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