

# emyria (ASX:EMD)

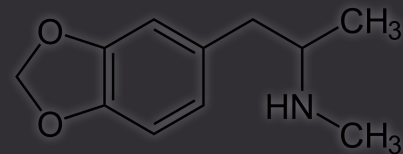
## MDMA-Inspired Drug Discovery

*Developing novel medicines for neuropsychiatric conditions, inspired by MDMA*

**13 Oct 2022** | Webinar

Dr Michael Winlo (Emyria)

Prof Matt Piggott (UWA)



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Presentation release authorised by Michael Winlo, CEO and Managing Director

# MDMA-INSPIRED DRUG DISCOVERY | EMYRIA & UWA

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**Michael  
Winlo**

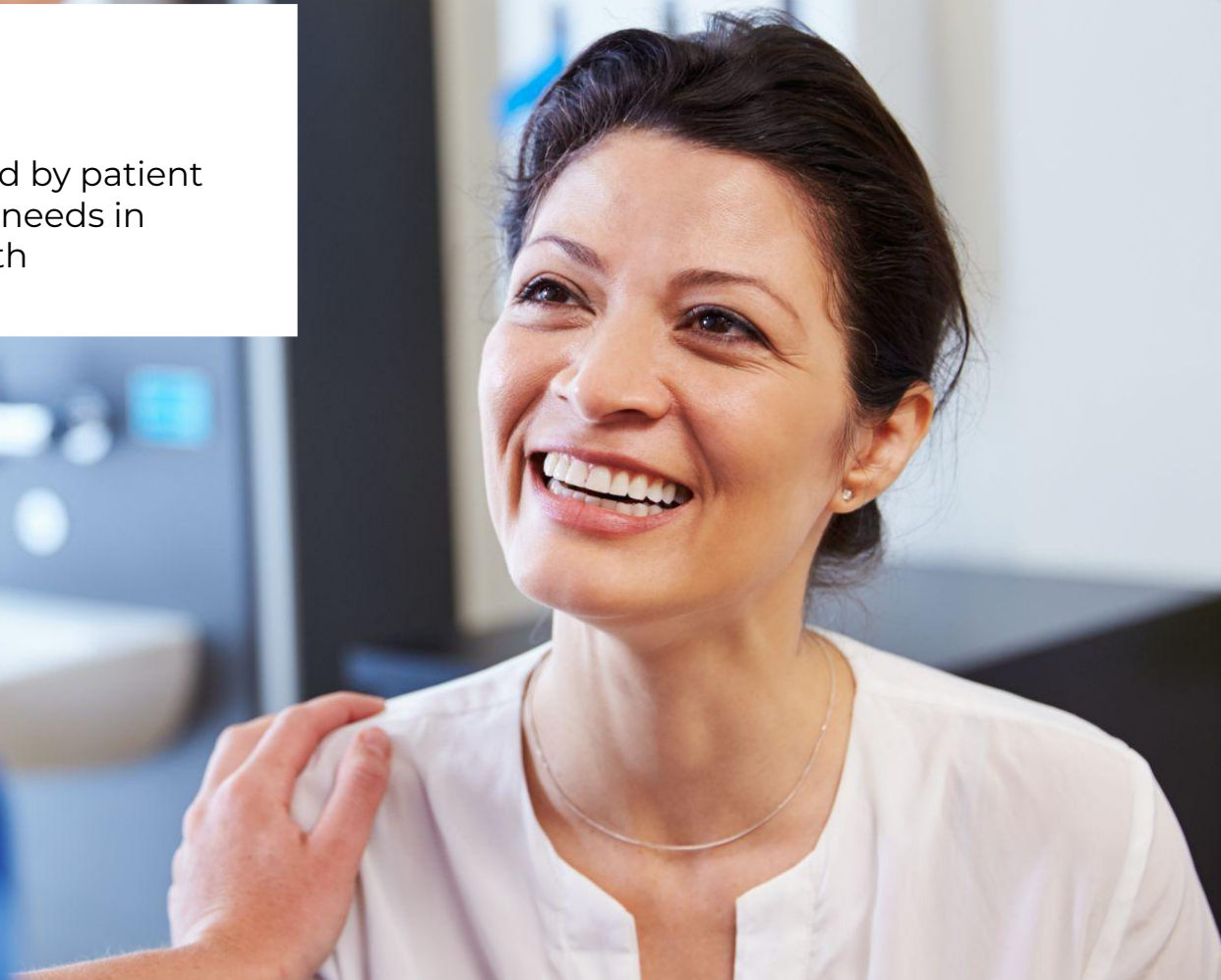
**Matt  
Piggott**



# emyria

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

mal use only



# emyria

An Australian  
public biotech  
company listed on  
the Australian  
Stock Exchange

(EMD:ASX) 2019

## CLINICAL FOCUS

Neuroscience and mental health



## LEADING PROGRAMS & TRACTION

### CLINICAL: ULTRA-PURE CANNABINOID MEDICINES

- Emyria's 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*

### 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*

## COMPARATIVE ADVANTAGES

- **Proprietary Real-World Data & tech** co-created with patients
- **A specialist clinical service** (*Emerald Clinics*)
- **Unique drug delivery platform**
- **Proprietary MDMA-inspired chemical entity library**
- **Global leadership** team with drug registration successes

## IP & PROTECTION

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

# EMYRIA | INVESTMENT HIGHLIGHTS

1

**Ultra-Pure cannabinoid** formulation technology, partnership ready

Demonstrated benefits over incumbent technologies. No THC or impurities; low patient variability; slow release and high bioavailability. Can support multiple dose forms and multiple indications.

2

**Advanced clinical programs**

**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

Dose response insights from **Real World Data (RWD)**

Emyria's clinical service, **Emerald Clinics**, gathers proprietary clinical data with patients that guides and de-risks indication selection, 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

**TODAY'S FOCUS**

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

**PATIENTS** to generate  
**CLINICAL DATA**

**&**

**GLOBAL EXPERTS** to create  
**NEW TREATMENTS** (*formulations & analogues*)

Continue **expanding** our well advanced proprietary cannabinoid Drug Development program - Ultra-Pure CBD

**Become a global leader in the development of neurological treatments inspired by MDMA**



THE GROWING INTEREST IN

# **PSYCHEDELIC ASSISTED THERAPY**

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# MENTAL HEALTH DISORDERS

“Affects **1 in 4**  
**People, Globally**”

## POST-TRAUMATIC STRESS DISORDER (PTSD)



**2 in 3**

**Veterans suffer from PTSD**

**20-30%** of PTSD sufferers show some response to pharmacotherapy

**50%** respond to any treatments.

**Remission rates are as low as 5%.**

HEROIC  
HONORABLE  
DEDICATED  
DUTY  
SERVICE  
BRAVE  
READY  
COMMITMENT  
COURAGEOUS  
SELFLESS  
INTEGRITY  
VALIANT

Cohen Veterans  
Network

## MAJOR DEPRESSION

**264  
million**



People **suffer depression** globally

**40-60%** show *some* response to pharmacotherapy

**50-80%** relapse after treatment stops

**Common side effects of antidepressants:**

Insomnia, psychosis, blurred vision, dry mouth, fatigue, GI distress, weight gain, nausea and sexual dysfunction



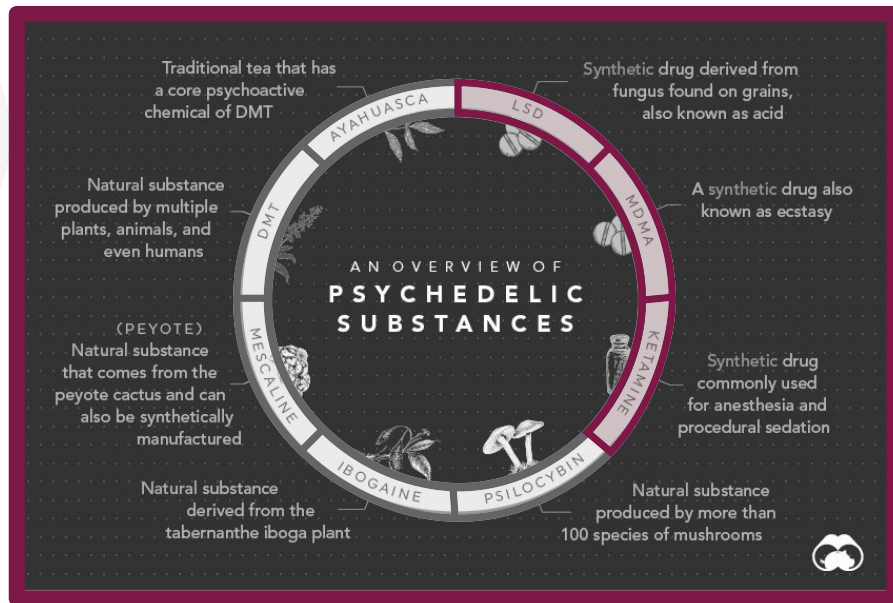
World Health  
Organization

# PSYCHEDELIC-ASSISTED THERAPY | WHAT IS IT?

Psychedelics alter communication between brain networks, such as the Default Mode Network (DMN), which are associated with many mental illnesses.

Thought to enable patients to break out of rigid styles of thinking, feeling and behaving.

Promotes a form of “active coping”, restoring patient agency and allowing supportive therapy to become more durable.



# NOVEL **PSYCHEDELIC MEDICINE** DEVELOPMENT IS ATTRACTING MAJOR INVESTMENT GLOBALLY



**\$100b**

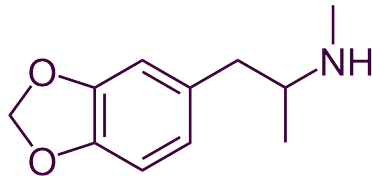
Estimated market for psychedelic medicines

| COMPANY                     | PROGRAMS + FOCUS   | MARKET CAP<br>(\$AUD) |
|-----------------------------|--|-----------------------|
| <b>RELMADA THERAPEUTICS</b> | <b>Esmethadone</b> (NMDAR antagonist), <b>psilocybin</b> (5HT2A) and esmethadone derivatives   | <b>\$1,600M</b>       |
| <b>GH RESEARCH</b>          | Exclusively focussed on <b>5-MeO-DMT</b> (5HT1A >> 5HT2A agonist)  | <b>\$940M</b>         |
| <b>ATAI LIFE SCIENCES</b>   | Parallel programs: <b>Psilocybin</b> , DMT (5HT2A receptor agonists), <b>MDMA-analogues</b> , arketamine, Ibogaine, Kratom, Salvinorin A   | <b>\$860M</b>         |
| <b>COMPASS PATHWAYS</b>     | <b>Psilocybin</b> , other 5HT2A agonists and unspecified compounds in development  | <b>\$780M</b>         |
| <b>MIND MEDICINE INC</b>    | 3 compounds in clinical development: <b>LSD</b> , <b>MDMA isomer</b> , and an <b>ibogaine</b> derivative. Novel preclinical stage phenethylamine, tryptamine, & ergoline derivatives | <b>\$400M</b>         |
| <b>emyria</b>               | MDMA-inspired drug discovery <u>AND</u> : Proprietary cannabinoid formulation development <b>in Phase 3 trials</b>   | <b>~\$60M</b>         |



WHAT IS **MDMA** ?

## WHAT IS MDMA?



### **MDMA (3,4-methylenedioxymethamphetamine or “ecstasy”)**

- an amphetamine that causes release of 3 neurotransmitters:

#### **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

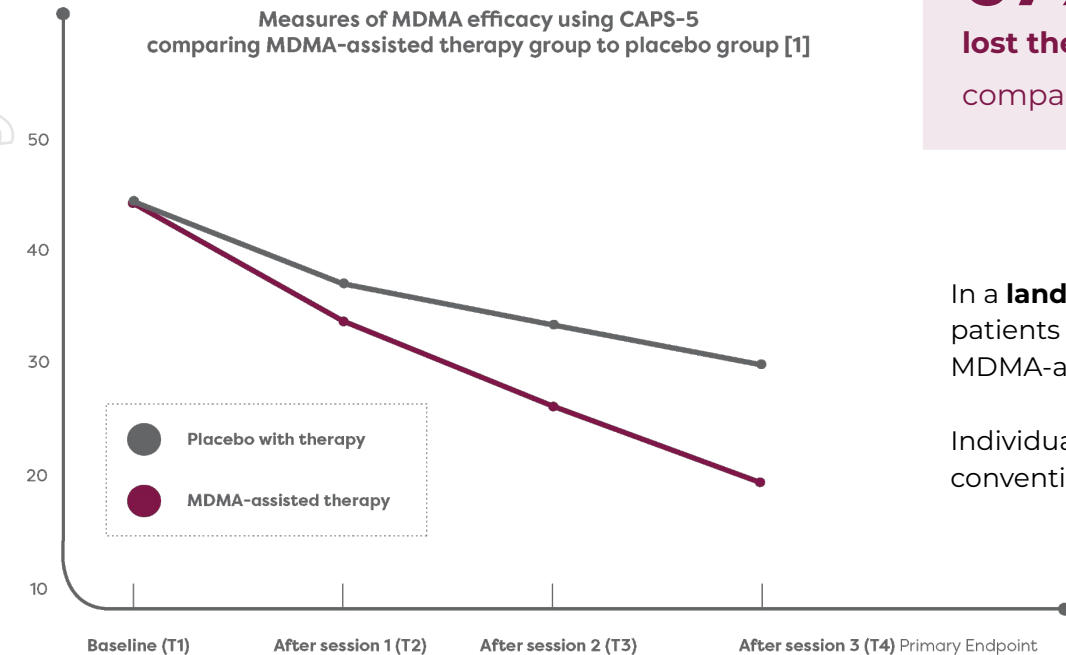


These effects suggest MDMA could be a promising **adjunct to psychotherapy** for a range of challenging MENTAL HEALTH CONDITIONS.

# THERAPEUTIC APPLICATIONS - MDMA-ASSISTED THERAPY FOR PTSD

CAPS-5 Total severity score

Measures of MDMA efficacy using CAPS-5 comparing MDMA-assisted therapy group to placebo group [1]



**67%** Of participants in the MDMA group **lost their PTSD diagnosis** following treatment, compared to **32%** in the therapy-only group.

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**.

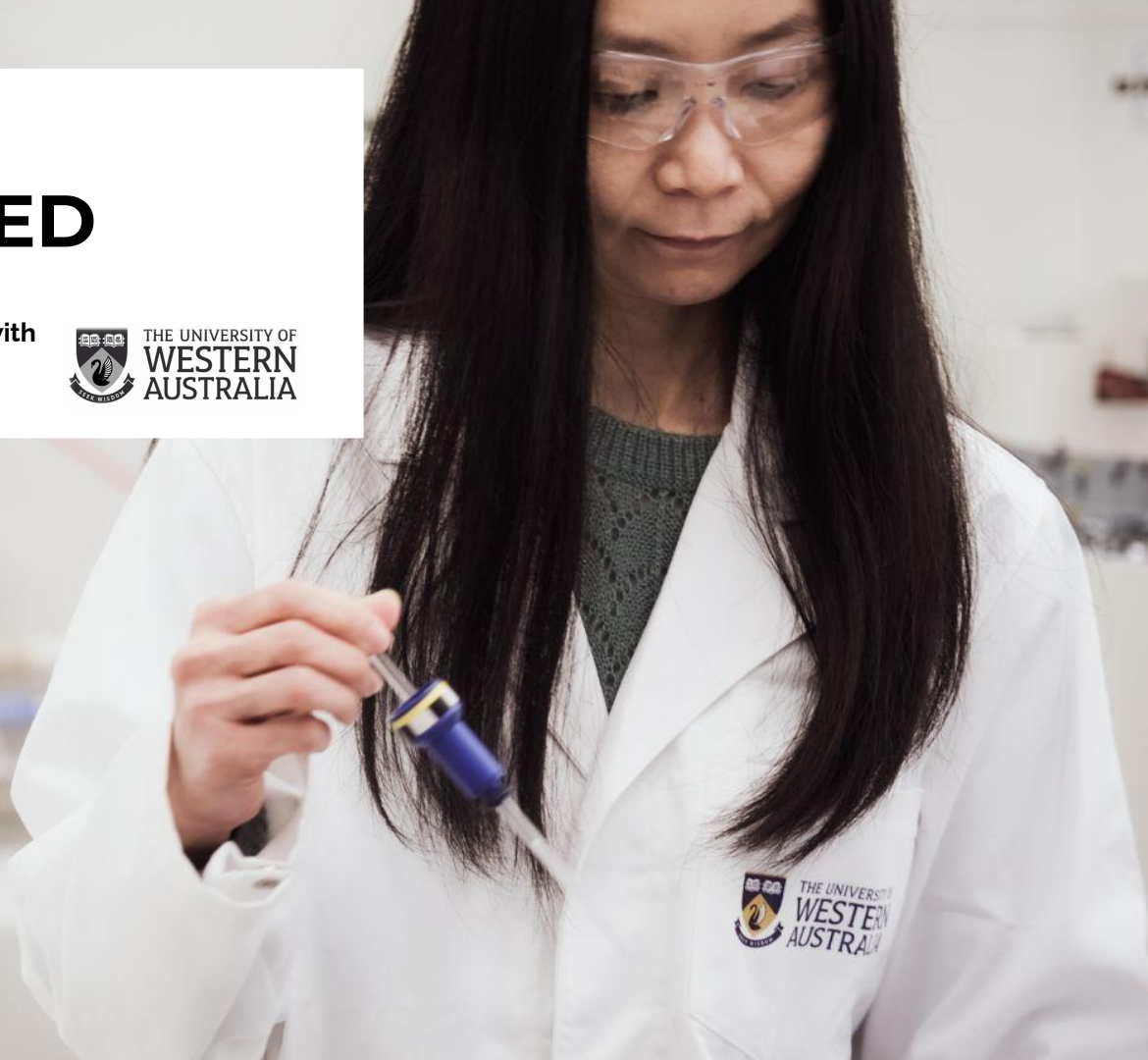


# MDMA-INSPIRED DRUG DISCOVERY

with



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# MDMA-INSPIRED DRUG DISCOVERY

NEW DRUG DEVELOPMENT

## WHY MDMA?

### Privileged chemistry

- Small, stable, brain-penetrating molecules
- Many points of diversification (create)

### Neurologically active

- MDMA hits many brain targets
- Opportunities to tune selectivity

### Promising adjunct to psychotherapy

- Receptiveness & positive mood
- Unique prosocial effects
- Effective adjunct to psychotherapy for PTSD (*but long, 8-12 hour sessions*)

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

## INNOVATION OPPORTUNITIES WITH MDMA-ANALOGUES

### Adjust metabolism?

- Shorter treatments
- Avoid potentially toxic metabolites

### Adjust neurological effects?

- Reduce stimulant “amphetamine effects”
- Moderate or remove euphoria

### New treatment opportunities?

- Improve safety of psychedelic-assisted therapy
- Shorter psychotherapy sessions
- Treatments for other neurological conditions

# MDMA-INSPIRED DRUG DISCOVERY | WORKFLOW

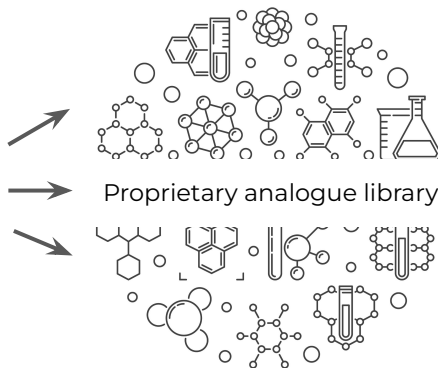
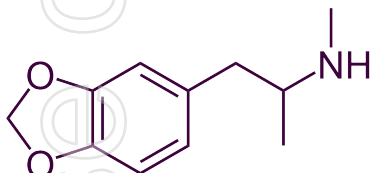
NEW DRUG DEVELOPMENT

Take MDMA  
as inspiration

Design and synthesise  
new compounds

Screen analogues  
(In vitro and In vivo)

Prioritise  
indications



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



Next-gen MDMA



Neuropsychiatric  
treatments

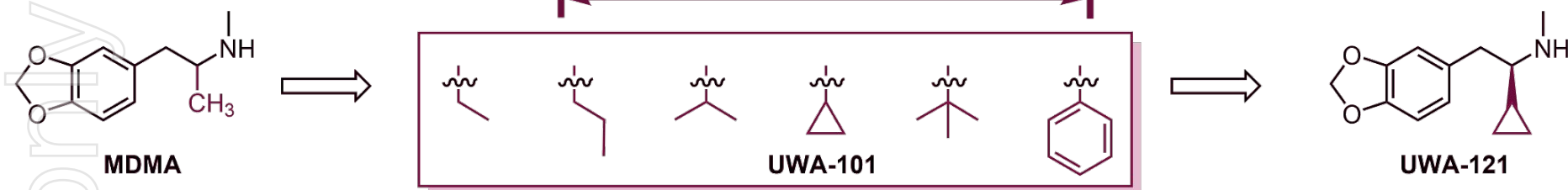


Non-neurological  
treatments

# CASE STUDY: UWA-121, an MDMA-analogue for Parkinson's disease

NEW DRUG DEVELOPMENT

Background Video



+ Profound improvement of PD therapy

- Psychoactivity unsuitable for a chronic condition

Small series of MDMA analogues evaluated in rat and primate models

Single enantiomer (mirror image) most promising

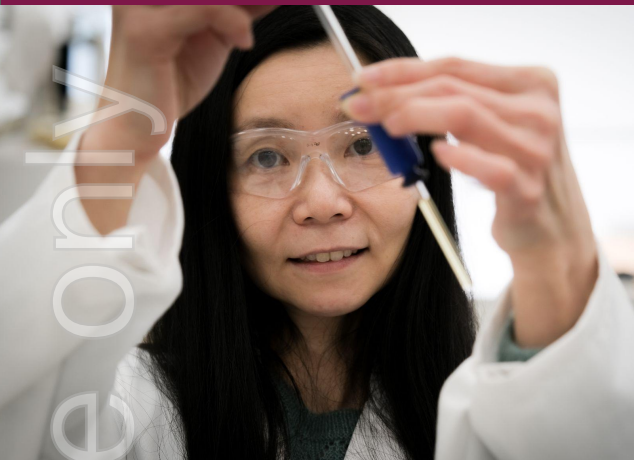
**In the gold-standard PD primate model, UWA-121:**

- Extends on-time by **40%**
- Increases 'good quality' on-time by **215%**

# THE UWA TEAM



THE UNIVERSITY OF  
**WESTERN  
AUSTRALIA**



**Dr Joelle Loh**  
*Analytical chemistry Data curation*



**Adam Fielding**  
*(Honours student)*



**Dr Glenn Pullella**  
*Design & Synthesis*



# PROGRESS

AND NEXT STEPS

with



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# MDMA-INSPIRED DRUG DISCOVERY | PROGRESS TO DATE

NEW DRUG DISCOVERY

with



## THE MDMA ANALOGUE LIBRARY

- **>140** unique MDMA analogues -created and characterised
- Ongoing synthesis and screening [1] (*grew 40% since partnership*)
- Very few with “off-target” effects
- Verified **excellent purity & stability**
- Multiple patent families
- Preclinical program launched



**LIBRARY EXCLUSIVELY  
OPTIONED TO EMYRIA**



# MDMA-INSPIRED DRUG DISCOVERY | POTENTIAL OF NEW TREATMENTS

| THERAPEUTIC CLASS   | RECEPTOR ACTION                             | COMMERCIALISED EXAMPLES   | MARKET SIZING (\$US)  |
|---|---|---|---|
| 5HT2B antagonists   | Antagonism of 5HT2B                         | <b>No approved selective 5HT2B antagonists</b><br>One company developing drugs for this target exclusively ( <b>Anamar</b> )  | <b>Fibrosis</b><br>Sales of <i>Esbriet</i> = <b>\$1.0b</b><br>Sales of <i>Ofeb</i> = <b>\$2.4b</b>          |
| Increased <b>dopamine</b> neurotransmission                   | More selective for <b>DAT</b> > NET or SERT | <b>Modafinil</b><br>(improves wakefulness in narcolepsy, OSA, shift work)   | <b>Narcolepsy</b><br>Sales of <i>Xyrem</i> + <i>Xywav</i> = <b>\$1.8b</b><br>Sales of <i>Sunosi</i> = \$58m |
| Increased <b>noradrenaline</b> neurotransmission              | More selective for <b>NET</b> > DAT or SERT | <b>Edronax</b> (Depression)<br><b>Strattera</b> (ADHD)<br><b>Qelbree</b> (ADHD, formerly depression)  | <b>Depression</b><br>8.9m US adults have medication treated depression 2.8m are treatment-resistant [1]     |
| Increased <b>dopamine and noradrenaline</b> neurotransmission | More selective for <b>DAT + NET</b> > SERT  | <b>Sunosi</b> (Daytime sleepiness due to Narcolepsy, OSA)<br><b>Ritalin</b> (Narcolepsy, ADHD)<br><b>Adderall</b> (Narcolepsy, ADHD)<br><b>Dexedrine</b> (Narcolepsy, ADHD) | <b>ADHD</b><br>~12m have ADHD in the US in 2021 [2], [3]  |

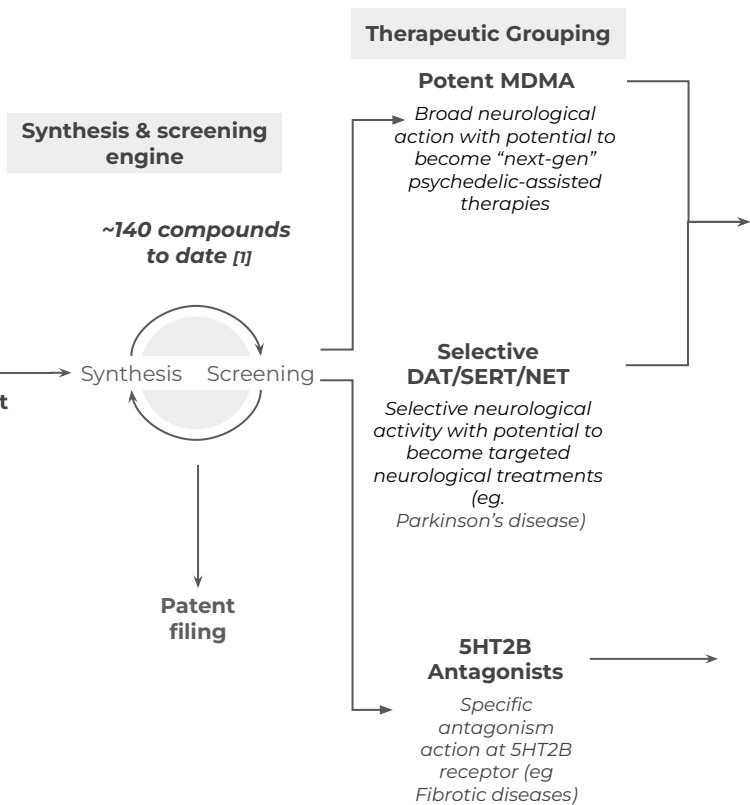
1. Zhdanova, M., Pilon, D., Gheleter, I., Chow, W., Joshi, K., Lefebvre, P., & Sheehan, J. J. (2021). The prevalence and national burden of treatment-resistant depression and major depressive disorder in the United States. *The Journal of Clinical Psychiatry*, 82(2), 29169.
2. Willcutt, E. G. (2012). The prevalence of DSM-IV attention-deficit/hyperactivity disorder: a meta-analytic review. *Neurotherapeutics*, 9(3), 490-499.
3. Fayyad, J., Sampson, N. A., Hwang, I., Adamowski, T., Aguilar-Gaxiola, S., Al-Hamzawi, A., ... & Kessler, R. C. (2017). The descriptive epidemiology of DSM-IV adult ADHD in the world health organization world mental health surveys. *ADHD Attention Deficit and Hyperactivity Disorders*, 9(1), 47-65.

# MDMA-INSPIRED DRUG DISCOVERY | PROMISING EARLY RESULTS

| THERAPEUTIC CLASS  | RECEPTOR ACTION                                     | # EMYRIA COMPOUNDS THAT DEMONSTRATE RECEPTOR ACTION |
|--|---|---|
| <b>5HT2B</b> antagonists   | <b>Antagonism</b> of 5HT2B                          | <b>Several</b>                                      |
| <b>Dopamine</b> reuptake inhibition (DRI)                            | More selective for <b>DAT</b> > NET or SERT         | <b>Several</b>                                      |
| <b>Norepinephrine</b> reuptake inhibition (NRI)                      | More selective for <b>NET</b> > DAT or SERT         | <b>Several</b>                                      |
| <b>Norepinephrine-dopamine</b> reuptake inhibition (NDRI)            | More selective for <b>DAT + NET</b> > SERT          | <b>Several</b>                                      |
| <b>Serotonin-norepinephrine-dopamine</b> reuptake inhibition (SNDRI) | <b>Nonselective</b> DAT/SERT/NET binding inhibition | <b>One</b>  |

# MDMA-INSPIRED DRUG DISCOVERY | SCREENING WORKFLOW

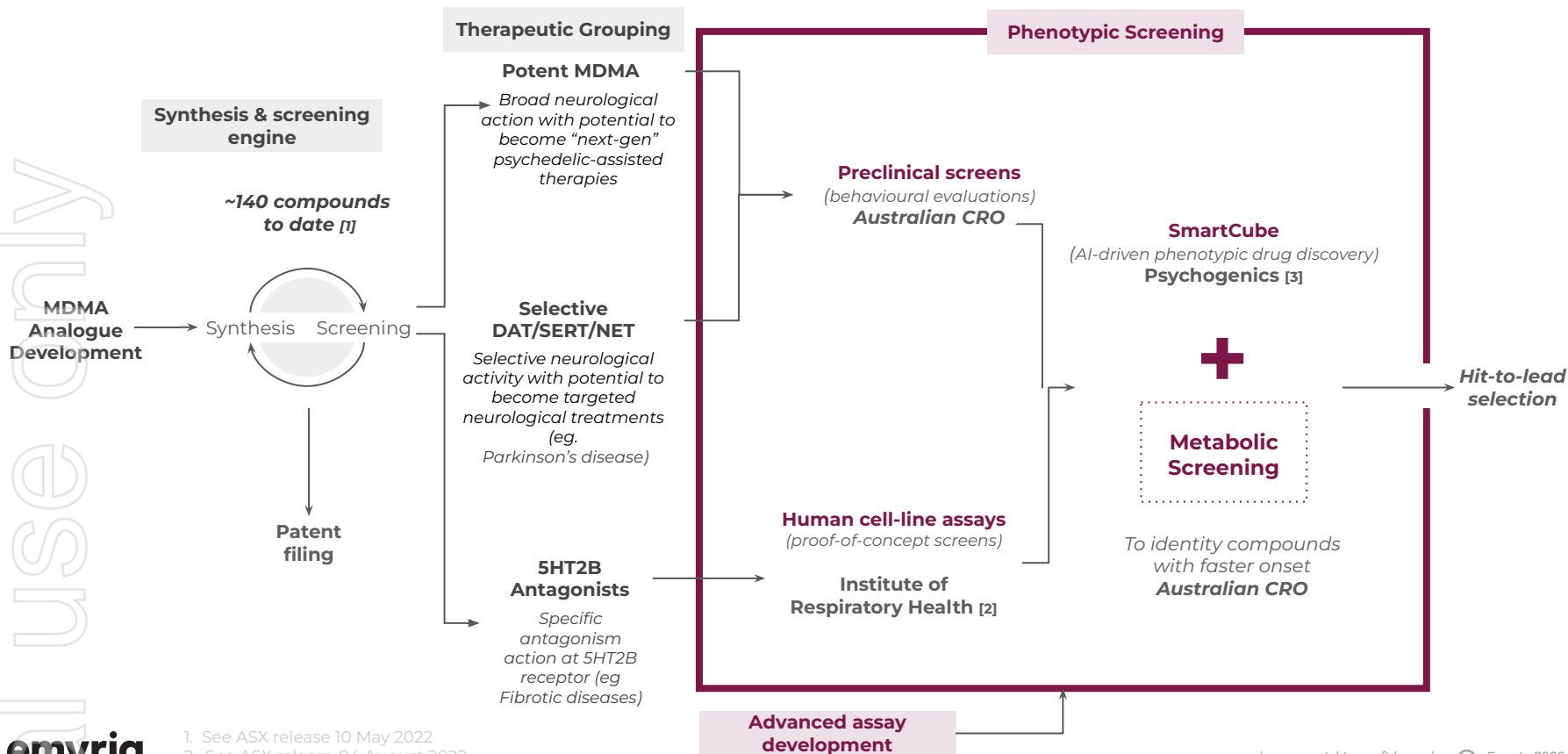
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1. See ASX release 10 May 2022.  
2. See ASX release 04 August 2022.  
3. See ASX release 19 September 2022.

# MDMA-INSPIRED DRUG DISCOVERY | PRECLINICAL WORKFLOW

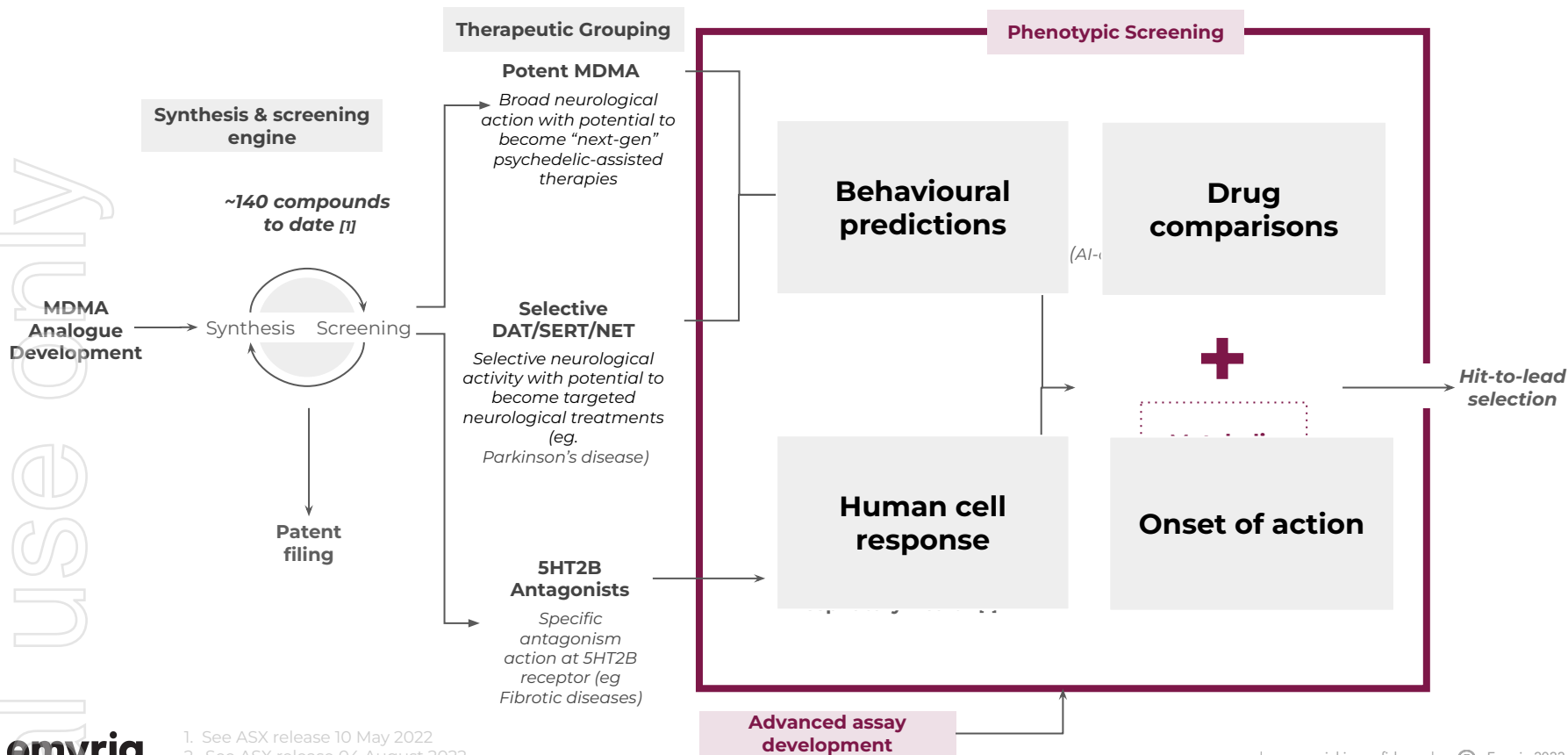
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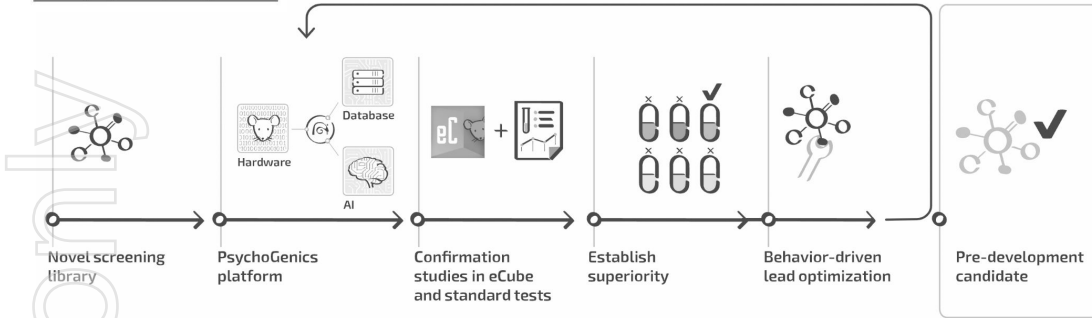
# MDMA-INSPIRED DRUG DISCOVERY | PRECLINICAL WORKFLOW

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3. See ASX release 19 September 2022

# ADVANCED PRECLINICAL SCREENING | SMARTCUBE<sup>(R)</sup> - computer vision and AI



SmartCube<sup>®</sup> is an automated testing platform that presents a sequence of challenges to a mouse and incorporates computer vision and AI to process and analyze more than half a million data points per mouse per session.

The SmartCube<sup>®</sup> platform uses proprietary bioinformatics to detect and assess the potential of compounds to treat psychiatric disorders in an unbiased way by comparing their complex behavioral profiles with those from a reference database at the drug class (primary therapeutic indication) and subclass (primary mechanism of action) level.

Q&A

## New partnership may give MDMA an edge in the psychedelics space

While LSD and psilocybin steal the spotlight, drug developers are also exploring MDMA for a wide swath of neurological illnesses.

Published Oct. 10, 2022

By Kelly Bilodeau



Stan Eales via Getty Images

# 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

Ongoing creation and  
in vivo screening

Hit-to-lead identification and dose from development

Preclinical Screening and Toxicology

Phase 1  
Clinical Trials

MDMA-A



# MDMA-INSPIRED DRUG DISCOVERY | SUMMARY

NEW DRUG DISCOVERY

BACKED BY UWA RESEARCH

## Emyria-UWA MDMA analogue library captures a unique chemical space with differentiated pharmacology

- **Largest reported database** of MDMA derivatives currently in development with >140 compounds in the library (*and growing*)
- **Compounds demonstrate diverse receptor binding profiles** on gold standard screening suggesting broad indication potential
- **Current list of potential indications spans major unmet needs in:**

**neuropsychiatry**

&

**anti-fibrosis**

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

*(currently undergoing preclinical assays)*

# Questions & Answers

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## CONTACT INFORMATION

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