# Emyria (ASX:EMD)

Hidden Gems Webinar | Michael Winlo, CEO

***Emyria*** *develops* ***biopharmaceuticals*** *guided by proprietary* ***Real-World Data*** *collected with patients across a wholly-owned clinical service subsidiary*

# Emyria provides care, generates data & develops treatments

Care → Data → Treatments

**5 clinical sites** (Emerald Clinics) treating more than **40 complex conditions** in **>6,000 patients** aged 2-98.

One of the **largest patient registries** of ethically sourced **Real-World Data** (RWD) on treatment effects of GMP-grade cannabinoids to guide biopharmaceutical development.

**2 FDA-compliant drug development programs** seeking **registration** with major global regulators. More in development.

Patients with unmet needs

New treatments

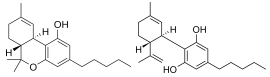
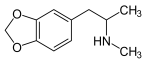
'Trial-grade' Real-World Data (RWD)

Dose response insights (IP)

Proprietary drug design

Global registration programs

# Emyria's active clinical development programs

| Platform | Active program | Initial opportunity | Next 3-6 months |
|---|---|---|---|
| **Ultra-pure cannabinoid-based medical treatments (CBMTs)**  | **EMD-RX5** — **Registration of first FDA-compliant CBD for multiple indications** | Over-the-counter treatment for psychological distress **$200m**/yr (Australia alone) <br> See ASX Announcement 19 October 2021 | * **Complete pivotal trials** <br> * **TGA registration application** <br> * **New formulations** <br> * **Launch US registration programs** |
| **Next-generation MDMA analogues**  | **MDMA *analogues*** — **Screen and expand library of novel MDMA analogues** <br> See ASX Announcement 19 October 2021 <br> THE UNIVERSITY OF WESTERN AUSTRALIA | Eg. Advanced treatment + therapies for PTSD **US$990m** / yr (Global) [1] | * **Advanced compound screening** <br> * **Commence animal studies** <br> * **Expand library** <br> * **Additional IP filings** |

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[1] https://www.coherentmarketinsights.com/market-insight/post-traumatic-stress-disorder-treatment-market-4433

# Biopharmaceutical cannabinoid development

# Extensive Real-World Data (RWD) on cannabinoid treatments:
## *6,000 patients and counting*

| | | | |
|---|---|---|---|
| ***What dose?*** → | **0-1,200** mg<br>Range of daily **CBD** prescribed | **0-197** mg<br>Range of daily **THC** prescribed | **7.12**<br>Average **concomitant medications** per patient at initial visit |
| ***What problem?*** → | **44**<br>Unique **primary indications** | **53%**<br>Patients presenting with symptoms of **depression** | **54%**<br>Patients presenting with symptoms of moderate to severe **anxiety** |
| ***Which patients?*** → | **2 - 98** years<br>**age range** of patients | **56%**<br>**female** patients | **35%**<br>Patients experiencing an **adverse event** |

**Data summary as of 28 FEB 2022**

# 40% of registered drugs are derived from plants

*Medicinal cannabis is stuck at* ***"2.0"***

| Medicine | *"1.0"* Natural origins | | *"2.0"* First medical use | Trials & registration | *"3.0"* True pharmaceutical | Commercialisation status |
|---|---|---|---|---|---|---|
| Statins |  | *Pleurotus ostreatus (oyster mushroom)* | **1970's** First discovered | **1987** *Synthetically* developed |  | **US$95bn** lifetime sales of Lipitor alone |
| Aspirin |  | *Salix alba (white willow)* | **~400 BCE** First prepared as a tea | **1899** |  | **US$750M USD** for "aspirin cardio" alone in 2020 |
| Cannabis |  | *Cannabis sativa (cannabis)* | **~8000 BCE** First medicinal use documented |  | **Emyria's novel synthetic delivery and drug development programs target multiple indications** | **Initial targets: mental health, insomnia and pain** |

https://www.fiercepharma.com/pharma/from-old-behemoth-lipitor-to-new-king-humira-u-s-best-selling-drugs-over-25-years

# Emyria's synthetic CBD vs comparators

ALTASCIENCES

**Emyria is developing a novel cannabinoid delivery platform with leading North American contract drug manufacturer Altasciences** (See ASX Announcement 13 August 2021)

| Feature | Emyria's proprietary formulation | Botanical alternatives |
|---|---|---|
| **Biological action** | *Synthetic CBD has **equivalent** physiological effects to botanical CBD [1]* | |
| **Regulatory considerations** | **FDA** Drug Master File for API. Acceptance from major regulators | Most CBD oils do not meet FDA requirements for CBD purity *(with exception of Epidyolex)* |
| **Chromatographic purity (low level, ppm)** | No detectable THC<br>**Synthetic API**<br>• Delta-9-THC < 4 (*ND)<br>• Delta-8-THC < 4 (*ND)<br>• Sum (D8,D9) < 4 (*ND) | THC present<br>**Epidyolex**<br>• 224<br>• 84<br>• 328 |
| **Enantiomeric purity by HPLC** | Ultra-pure<br>**Synthetic API**<br>• (-)-CBD 100%<br>• (+)-CBD 0.00% | **Epidyolex**<br>• 99.9%<br>• 0.08% |
| **Enhancing bioavailability** | Emyria technology achieves ~1.5-2x greater (c/w Epidyolex) | Generally poor BA. Sesame oils > MCT oils |
| **Intellectual property** | 100% Emyria-owned | Generic oils - limited IP |
| **Costs** | Cost effective over long-term | Plant extraction expensive |

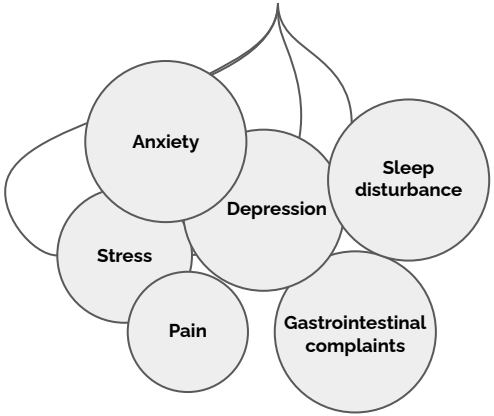
1. Maguire R, F, Wilkinson D, J, England T, J, O'Sullivan S, E: The Pharmacological Effects of Plant-Derived versus Synthetic Cannabidiol in Human Cell Lines. Med Cannabis Cannabinoids 2021. doi: 10.1159/000517120

# EMD-RX5: ultra-pure CBD

*Targeting multiple indications*

# First indication: *Psychological distress* - a growing challenge

Symptoms of **psychological distress**




More prevalent in patients with **chronic disease**

**~15% of Australian adults** experience high or very high levels of psychological distress [1].

**Prevalence is increasing**. [2]

**Current treatments** may include monitoring, psychotherapy, prescription medications or referral to support services. [3]

***There is no over-the-counter treatment for psychological distress.***

[1] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW.
[2] https://www.frontiersin.org/articles/10.3389/fpsyt.2020.595696/full
[3] https://onlinelibrary.wiley.com/doi/pdf/10.1111/scs.12289



BRIEFING ROOM

# FACT SHEET: President Biden to Announce Strategy to Address Our National Mental Health Crisis, As Part of Unity Agenda in his First State of the Union

MARCH 01, 2022 • STATEMENTS AND RELEASES

In his first State of the Union, the President will outline a unity agenda consisting of policy where there has historically been support from both Republicans and Democrats, and call on Congress to send bills to his desk to deliver progress for the American people. As part of this unity agenda, he will announce a strategy to address our national mental health crisis.

Our country faces an unprecedented mental health crisis among people of all ages. Two out of five adults report ↗symptoms of anxiety or depression. And, Black and Brown communities are disproportionately ↗ ↗ undertreated – even as their burden of mental illness has continued to rise. Even before the pandemic, rates of depression and anxiety were inching higher ↗. But the grief, trauma, and physical isolation of the last two years have driven Americans to a breaking point ↗.

THE WHITE HOUSE

Administration Priorities COVID Plan Briefing Room Español

BRIEFING ROOM

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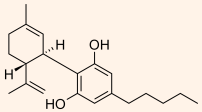
# Developing an over-the-counter cannabinoid medicine for psychological distress (EMD-RX5)

**Access:**
Registered "over-the-counter" (OTC) treatments **do not require a doctor's prescription**.

Registered OTC treatments can be **purchased directly** from qualified **pharmacists**.

There are **5,900 pharmacies in Australia.** [1] and **OTC market** is estimated at over **$20B/year** [2].




The TGA permits **low-dose cannabidiol (CBD)** to be registered as Schedule 3 (S3) OTC medicine. [3]
**S3 cannabinoid medicines** could generate an estimated **$200m** in Australia, much more globally. [4]

**Emyria plans to register one of the first, affordable, cannabinoid S3 medicines (EMD-RX5)**

**EMD-RX5 will initially target psychological distress but poised to expand to adjacent indications**



[1] https://www.guild.org.au/__data/assets/pdf_file/0020/12908/Vital-facts-on-community-pharmacy.p
[2] https://insights10.com/product/australia-otc-market-analysis
[3] See ASX announcement 16 December 2021
[4] https://freshleafanalytics.com.au

# EMD-RX5: Real World Data helps with indication selection

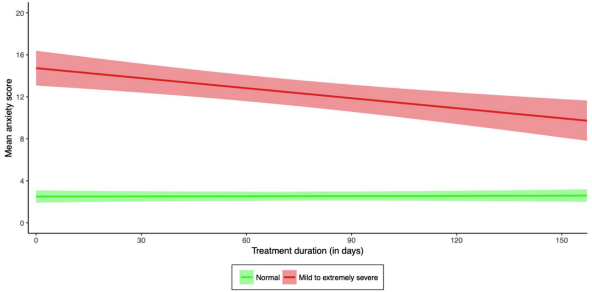
Care → Data → Treatments

Emyria has generated **Real World Evidence (RWE)** on more than 600 patients receiving > 6 months treatment on **low-dose CBD** for **psychological distress**.

Data analysis revealed a specific **dose-response**, for a specific set of indications, in a specific patient population.

Data insights support **patents** (*see slide 22*), the development of **EMD-RX5** and **Emyria's registration program**

**600+** patients




[1] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW.
[2] https://www.frontiersin.org/articles/10.3389/fpsyt.2020.595696/full
[3] https://onlinelibrary.wiley.com/doi/pdf/10.1111/scs.12289

# EMD-RX5: Rapid clinical development progress

*Commences March*

| 1 ✔ | 2 ✔ | 3 ✔ | 4 |
|---|---|---|---|
| **Formulation design** | **Preformulation studies** | **Dog PK study** | **Phase 1** *(dosing March, 22)* |
| • Synthetic CBD (full DMF)<br>• FDA-approved excipients<br>• FDA-compliant CBD purity (*c/w TGA purity requirements*)<br>• Capsule dose form<br>• Reliable dosing<br>• Stable at room temp<br>• Increased bioavailability<br>• Cost effective<br>• Unique IP | • Dissolution studies<br>• Qualification of formula<br>• Excipient testing with validated method<br>• = Leading formulations evaluated in pre-clinical PK study | • Comparison to Epidyolex<br>• Full PK assessments *(eg Tmax, Cmax, AUC, AEs)*<br>• = EMD-RX5 appears to have superior bioavailability compared to Epidyolex [1] | • **Ethics approval [2]**<br>• 12 subject, HNV<br>• 2-way crossover *(Epidyolex + EMD-RX5)* |

- ***Pivotal Phase 3 clinical trials are fully planned***

✔ **ICH-GMP-compliant manufacturing**

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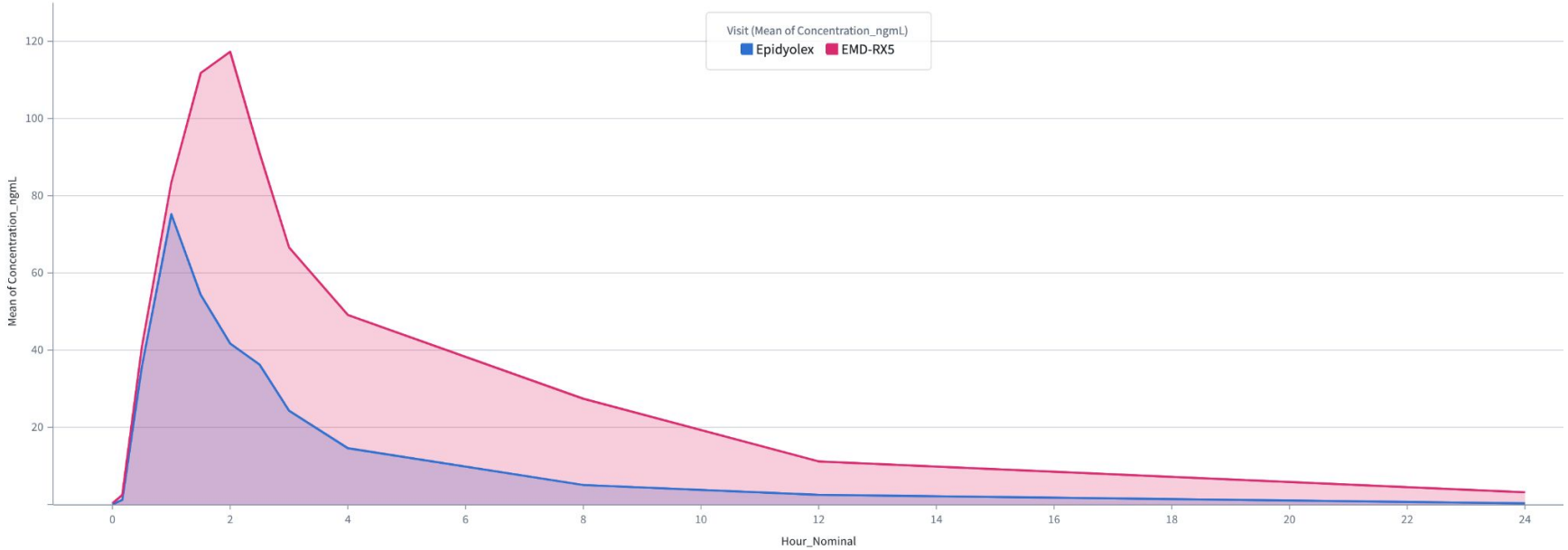
[1] See ASX announcement 15 December 2021
[2] See ASX announcement 03 March 2022

# EMD-RX5: Greater bioavailability compared to Epidyolex



# EMD-RX5: *What's next?* New indications. More formulations.

## 1 Ongoing RWD collecting & analysis

- Dose-response insights on >6,000 patients and growing
- Long-term AE monitoring

Helps inform:

- Additional indication selection
- Pivotal study designs *(eg. endpoint selection)*
- Dose form preferences

## 2 Proprietary dose-form development, if required

- **CBD-only** (eg. EMD-RX5)
- **CBD/THC combinations**

## 3 Launch drug registration programs

- **EMD-RX5** (multiple indications)
  - Distress
  - IBS
  - *Others*
- ***Others in development***

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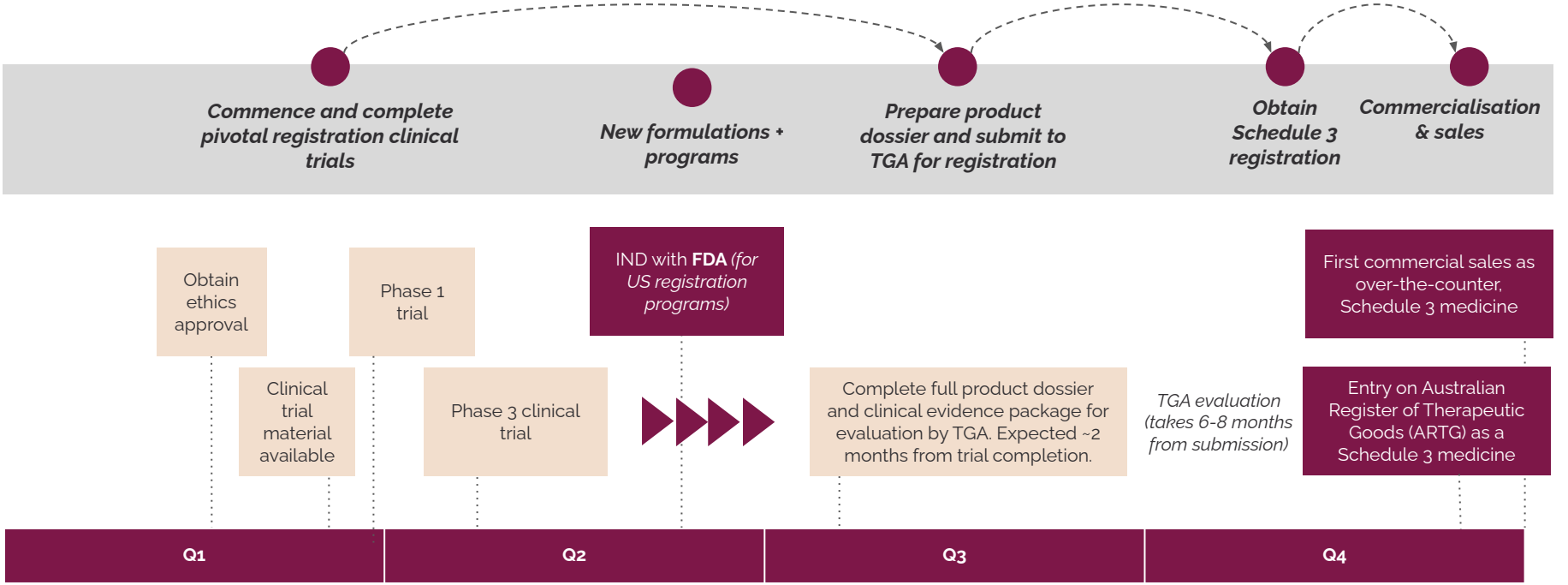
# Cannabinoid program development milestones



# Leading next generation psychedelic development

# Psychedelic-assisted therapy addressing major unmet needs and attracting large investment

**$100b**
Estimated market for psychedelic medicines
Canaccord Genuity

**264m**
Number of people who suffer depression globally
World Health Organization

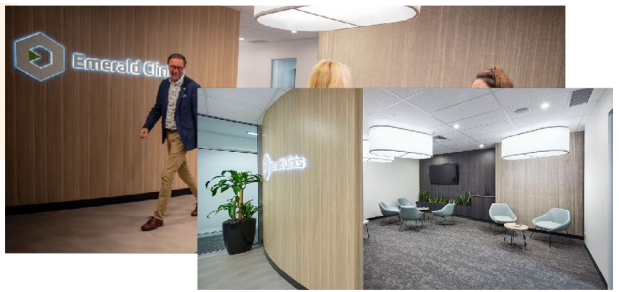
**$10.2b (AUD)**
Aggregate market cap of psychedelic drug companies
yahoo! finance

**2 in 3**
Veterans suffer from PTSD
Cohen Veterans Network

**1 in 4**
People in the world are affected by mental health disorders
World Health Organization

# Emyria positioned to lead in treatment development

*Emyria can leverage an **established clinical sites** and **provider network,** an **experienced in-house drug development team** and also has access to **unique treatment assets***

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# MDMA analogue development

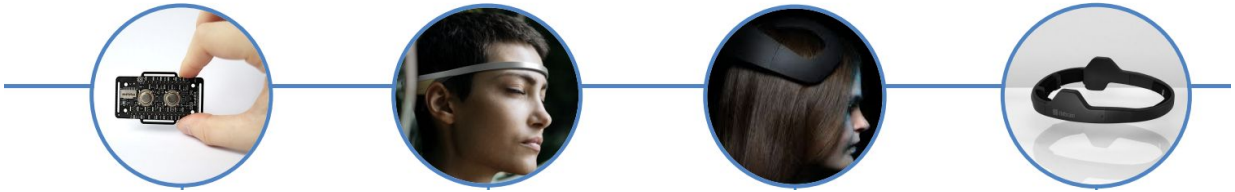
# Emyria's MDMA analogue library - a drug discovery pipeline

| Emyria's MDMA analogue library | |
|---|---|
| **Key features** | • **>100** unique MDMA analogues, *and growing* [1]<br>• **>10 years of development** at UWA<br>• Entire library exclusively optioned to Emyria<br>• Verified **excellent purity and stability**<br>• Potential as treatments for:<br>  ○ Next-gen psychedelics, neurological disorders + *other conditions* |
| **Progress to date** | 1. No "off-target" effects in first screen *(~66 compounds)* [2]<br>2. First patent filed<br>3. Library expansion underway<br>4. University of +Sydney engaged to develop animal models [2]<br>5. ***NEXT**: Further expansion, screening and evaluation* |


[1] See ASX announcement 05 August 2021
[2] See ASX announcement 08 December 2021

# Emyria's clinical research

# EMDMA-001: a Phase IIa trial for PTSD with advanced monitoring



Screening | Preparation | Drug treatment + non-drug psychotherapy: Cycle 1, Cycle 2, Cycle 3 | Follow-Up

Duration = 18 months

EMDMA-001 to evaluate potential of MDMA-assisted therapy for additional patients.

Will involve advanced remote monitoring technology with partner **Cydelic** [1].

Protocol completed and clinical psychologists have completed MAPS training *as well as* Certificate of Psychedelic-Assisted Therapies (CPAT) with partner, Mind Medicine Australia (MMA).

*The study will be led by consultant psychiatrist **Dr Eli Kotler** (left), and will be run out of the Victorian Counselling and Psychology Services in **Melbourne** (below)*

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[1] See ASX announcement 20 December 2021

# Emyria's growing patent portfolio

| | Title | Official No. | Status |
|---|---|---|---|
| **Emyria's cannabinoid patents cover unique formulations, delivery approaches and "method of use"** | 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-Related Psychological Distress | 2021901672 | Provisional filed |
| | Use Of Cannabinoid Combination for the Treatment of Irritable Bowel Syndrome-Related Psychological Distress | 2021901674 | Provisional filed |
| | Cannabidiol Dosing Regime | 2021902001 | Provisional filed |
| | Cannabinoid Dosage Form | 2022900479 | Provisional filed |
| | Analogues | 2021903836 | Provisional filed |
| | *Others in development covering unique delivery platforms, dose responses and clinical indications* | *Multiple provisionals expected 2021* | |

# Corporate structure

# Board has multiple drug registrations, deep biotech experience

**Dr Stewart Washer**
Chairman & Founder

**Prof Sir John Tooke**
Non-Executive Director

**Dr Karen Smith**
Executive Director
> 100 clinical trials & **20 FDA approvals**

**Matt Callahan**
Non-Executive Director
**4 FDA approvals**

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

**Dr Michael Winlo**
Managing Director

# Capital structure

**Top 20 = 60.48% | Tattarang holds ~5% [1]**
**Director ownership = 27.17%**

| Key Metrics | Value |
|---|---|
| Shares on issue | 254m |
| Last close ( 26 Oct 2021) | A$0.33 |
| **Market Capitalisation (26 Oct 2021)** | **A$90.75M** |
| Cash (31 Dec 2021) | A$8.7m |
| Debt (31 Dec 2021) | - |
| **Enterprise value** | **A~$82.05m** |
| Total options (exercise price $0.114-0.45) *expiring. 2022-24* | 62m |

# Share price over 12 months


Source: https://emyria.com/for-investors/#Stock-Information

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[1] See ASX announcement 22 November 2021

# Emyria positioned for growth

**1 World-class Board/Management with FDA registration successes**

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

**2 Proprietary data, access to clinics and patients**

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

**3 Targeting major markets and unmet needs**

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

**4 Unique biopharmaceutical cannabinoid platform**

Ultra-pure CBD dose form, FDA-compliant and with **bioavailability advantages**

**5 Leader in development of novel MDMA-analogues**

Exclusive access to large and **novel MDMA analogue compound library**

**6 Attractive valuation**

Compared to industry vertical peers